Import Alert 66-40

# **Import Alert 66-40**

f SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/CMS\_IA/IMPORTALERT\_189.HTML)

¥ TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=IMPORT ALERT 66-40&URL=HTTPS://WWW.ACCESSDATA.FDA.GOV/CMS\_IA/IMPORTALERT\_189.HTML)

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■ EMAIL (MAILTO:?SUBJECT=IMPORT ALERT 66-40&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/CMS\_IA/IMPORTALERT\_189.HTML)

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 66-40
Published Date: 07/01/2019

Type: DWPE

## **Import Alert Name:**

"Detention Without Physical Examination of Drugs From Firms Which Have Not Met Drug GMPs"

## **Reason for Alert:**

\*\*\* Foreign inspections of pharmaceutical manufacturers are being performed. Detention without physical examination may be appropriate when an FDA inspection has revealed that a firm is not operating in conformity with current good manufacturing practices (GMP's).

Detention without physical examination may also be appropriate when FDA receives information concerning inspections conducted by foreign or other government authorities under a Memorandum of Understanding or other agreement that FDA concludes reveals conditions or practices warranting detention of either particular products or all products manufactured by a firm.

DWPE of such firms remains in effect until such time as FDA is satisfied that the appearance of a violation has been removed, either by reinspection or submission of appropriate documentation to the responsible FDA Center. \*\*\* Note: Charge statement revised on 04/23/2019

## **Guidance:**

\*\*\* Districts may detain, without physical sampling and analysis, the indicated drug products from the foreign processors noted in the Red List of this import alert.

Foreign processors listed on the Red List of this import alert who would like to request removal from that list should provide information to FDA to adequately demonstrate that the manufacturer has resolved the conditions that gave rise to the appearance of the violation, so that the agency will have confidence that future entries will be in compliance. This may include a letter detailing its corrective actions, accompanied by documentation. For guidance on removal from detention without physical examination, refer to FDA se Regulatory Procedures Manual, Chapter 9, "Detention Without Physical Examination (DWPE)." Information supporting removal should be sent to CDER's Office of Compliance, (HFD-300). \*\*\*

## **Product Description:**

Various drugs (See attachment)

## Charge:

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods used in and controls used for the manufacture, processing, packing, or holding of drugs and other products do not appear to conform to current good manufacturing practices within the meaning of Section 501(a)(2)(B)."

OASIS Charge Code: DRUG GMPS

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

#### **AUSTRALIA**

Date Published: 09/28/2017 **Delta Laboratories Pty Ltd** 8 Warringah CL, Somersby, New South Wales AUSTRALIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2017 Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/28/2017 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices Jalco Cosmetics Pty Ltd. Date Published: 03/08/2018 45 King Rd, Hornsby, New South Wales AUSTRALIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/08/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/08/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products

## Radpharm Scientific

57 Oatley Court, Belconnen, AUSTRALIA

66 V I P 99 Miscellaneous Patent Medicines, Etc., Human - Investigational, Small Volume Parenteral <100ml

Notes: Nexavir

#### **AUSTRIA**

## Schrofner Cosmetics Gmbh

Robinigstrase 26a, Salzburg, Salzburg AUSTRIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 10/20/2017

Date Published: 10/20/2017

60 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 10/20/2017

## **BELGIUM**

Laboratoria Qualiphar NV Rijksweg 9, Bornem, Antwerp BELGIUM 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All drug products 60 - - - - Human and Animal Drugs Notes: All drug products 61 - - - - Human and Animal Drugs

Notes: All drug products

62 - - - - Human and Animal Drugs Notes: All drug products

63 - - - - Human and Animal Drugs

Notes: All drug products

64 - - - - Human and Animal Drugs

Notes: All drug products

65 - - - - Human and Animal Drugs

Notes: All drug products

66 - - - - Human and Animal Drugs

Notes: All drug products

Date Published: 01/18/2011

#### **BRAZIL**

#### Lima & Pergher Ind. Com. Rep Ltda

Av Airton Borges Da Silva 740, Minas Gerais, BRAZIL

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 07/15/2016

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Lima & Pergher Industria e Comercio S/A

Rua Engenheiro Diniz 2069, B. Martins, Uberlandia, Minas Gerais BRAZIL

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 07/15/2016

## CANADA

Aleeda Inc 7115 Tomken Rd , Mississauga, Ontario CANADA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

#### Attix Pharmaceuticals Inc.

184 Front St Unit 801, Toronto, Ontario CANADA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs

04 - - - - numan and Animai Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 65 - - - - - Human and Animal Drugs

oo - - - -- Human and Animai Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices

Aztex Enterprises Ltd.

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012 Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published. 05/29/2012

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Date Published: 05/29/2012

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Date Published : 02/18/2015

Date Published: 02/18/2015

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Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 10/19/2017

5155 Fairview Street, Burlington, Ontario CANADA 53 - - - - Cosmetics Date Published: 10/19/2017 Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/19/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products Date Published: 10/19/2017 Aztex Enterprises Ltd. 5155 Fairview Street, Burlington, Ontario CANADA Date Published: 10/19/2017 53 - - - - Cosmetics Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/19/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/19/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products **Baxter Healthcare** Date Published: 04/10/2014 Unknown Street, Mississauga, ON CANADA 55 R - - 55 Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent) Date Published: 04/10/2014 Desc: 0.9% Sodium Chloride Injection USP 65 R - - 12 Potassic Saline (Injection) (Replenisher) Date Published: 04/10/2014 Desc: 0.9% Sodium Chloride Injection USP Bill Beauty and Health Products Ltd. Date Published: 07/24/2018 120 Silver Star Blvd, Scarborough, Ontario CANADA 53 S - - -- Cosmetic Prods Containing Animal By Prod (Ovine) Date Published: 07/24/2018 Desc: All Drug and Drug Products Notes: For industry code 53S and 54B; only products found to be drug products are subject to DWPE under this listing. Date Published: 07/24/2018 54 B - - -- Mineral Desc: All Drug and Drug Products Notes: For industry code 53S and 54B; only products found to be drug products are subject to DWPE under this listing.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products

Date Published: 07/24/2018

56 - - - - Antibiotics (Human/Animal) Date Published: 07/24/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 07/24/2018 Notes: All Drug and Drug Products **CMI Cosmetic Manufacturers Inc.** Date Published: 09/28/2015 90 Moyal Court, Concord, On CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/28/2015 Notes: (GMP) Good Manufacturing Practices Cellex-C International Inc. Date Published: 06/02/2017 9 New St, Toronto, Ontario CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/02/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/02/2017 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products

Centre for Probe Development & Commercialization
Nrb A316, 1-1280 Main St W, Hamilton, Ontario CANADA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

63 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

Date Published : 08/01/2018

Date Published: 08/01/2018

Date Published: 06/02/2017

Date Published: 06/02/2017

Date Published: 06/02/2017

Date Published: 06/02/2017

Notes: All Drug and Drug Products; 56 - - - - Antibiotics (Human/Animal) Date Published: 08/01/2018 Notes: All Drug and Drug Products; 57 - - - - Bio & Licensed In-Vivo & In-Vitro Diag Date Published: 08/01/2018 Desc: All Drug and Drug Products Notes: For industry code 57; only products found to be drug products are subject to DWPE under this listing.; 60 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; 61 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; 62 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; 63 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; 64 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; 65 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; 66 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products; **Deserving Health International Corp** Date Published: 11/02/2017 13160 Vanier PI Unit 110, Richmond, British Columbia CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Gemini Packaging Ltd. Date Published: 12/10/2015 12071 Jacobson Way, Richmond, British Columbia CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 12/10/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Homeocan Inc Date Published: 05/03/2017 3025 Del Assomption, Lasalle, QC CANADA 53 - - - - Cosmetics Date Published: 05/03/2017 Desc: All Drugs and Drug Products Notes: Problem(s); (GMP) Good Manufacturing Practices 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Date Published: 05/03/2017 Homeocan Inc 3025 Del Assomption, Lasalle, QC CANADA 53 - - - - Cosmetics Date Published: 05/03/2017 Desc: All Drugs and Drug Products Notes: Problem(s); (GMP) Good Manufacturing Practices 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/03/2017 Desc: All Drugs and Drug Products Notes: Problem(s); (GMP) Good Manufacturing Practices 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 05/03/2017

61 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 05/03/2017

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Homeolab USA Inc. Date Published: 05/03/2017 3025 De l'Assomption Blvd, Montreal, Quebec CANADA 53 - - - - Cosmetics Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 05/03/2017 Notes: All Drugs and Drug Products; Problem(s); (GMP) Good Manufacturing Practices Lernapharm (Loris) Inc. Date Published: 04/24/2018 2323 Halpern St, Saint-Laurent, Quebec CANADA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/24/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 04/24/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 04/24/2018 Notes: All Drug and Drug Products 75 P - - QD Blood specimen collection convenience kit (excludes HIV) Date Published: 08/07/2018 Desc: All Drug and Drug Products Notes: For Industry Codes 75 and 80; only drug and drug products are subject to DWPE under this notice. 80 L - - KB Pad, alcohol, device disinfectant Date Published: 08/07/2018

Desc: All Drug and Drug Products

Notes: For Industry Codes 75 and 80; only drug and drug products are subject to DWPE under this notice.

Notes. For industry Codes 75 and 60, only drug and drug products are subject to DWFE under this hotice.	
Pax-All Manufacturing Inc	Date Published : 02/23/2012
5000 Howard Business Parkway , Windsor, On CANADA 55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 02/23/2012
Notes: All Drug Products 60 Human and Animal Drugs	Date Published: 02/23/2012
Notes: All Drug Products	Date i ublished. 02/25/2012
61 Human and Animal Drugs Notes: All Drug Products	Date Published: 02/23/2012
62 Human and Animal Drugs	Date Published: 02/23/2012
Notes: All Drug Products 63 Human and Animal Drugs	Date Published: 02/23/2012
Notes: All Drug Products	Date 1 ubilibried. 02/20/2012
64 Human and Animal Drugs Notes: All Drug Products	Date Published: 02/23/2012
65 Human and Animal Drugs	Date Published: 02/23/2012
Notes: All Drug Products	Data Bublishad: 02/22/2012
66 Human and Animal Drugs Notes: All Drug Products	Date Published: 02/23/2012
Petra Hygienic Systems Int Ltd	Date Published : 03/25/2019
86 Moyal Crt , Concord, Ontario CANADA	Date Fublished . 03/23/2013
53 J 01 Bath Soaps and Detergents (not Antiperspirant) (Personal Cleanliness)	Date Published: 03/25/2019
Desc: All Drug and Drug Products  Notes: For 53J[[[]01; only drug and drug products (i.e. anti-bacterial soap) are subject to DWPE under this notice.	
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 03/25/2019
Notes: All Drug and Drug Products 56 Antibiotics (Human/Animal)	Date Published: 03/25/2019
Notes: All Drug and Drug Products	D-4- D-4-1-1-1-1-00/05/0040
60 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 03/25/2019
61 Human and Animal Drugs	Date Published: 03/25/2019
Notes: All Drug and Drug Products 62 Human and Animal Drugs	Date Published: 03/25/2019
Notes: All Drug and Drug Products	
63 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 03/25/2019
64 Human and Animal Drugs	Date Published: 03/25/2019
Notes: All Drug and Drug Products	
65 Human and Animal Drugs 66 Human and Animal Drugs	Date Published: 03/25/2019 Date Published: 03/25/2019
Ross Healthcare Inc.	Date Published : 11/30/2017
6-1520 Cliveden Ave , Delta, British Columbia CANADA	Date i ublished : 11/30/2017
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 11/30/2017
Notes: All Drug and Drug Products 56 Antibiotics (Human/Animal)	Date Published: 11/30/2017
Notes: All Drug and Drug Products	
60 Human and Animal Drugs	Date Published: 11/30/2017
Notes: All Drug and Drug Products 61 Human and Animal Drugs	Date Published: 11/30/2017
Notes: All Drug and Drug Products	
62 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 11/30/2017
63 Human and Animal Drugs	Date Published: 11/30/2017
Notes: All Drug and Drug Products	
64 Human and Animal Drugs	Date Published: 11/30/2017
Notes: All Drug and Drug Products 65 Human and Animal Drugs	Date Published: 11/30/2017
Notes: All Drug and Drug Products	
66 Human and Animal Drugs	Date Published: 11/30/2017

Notes: All Drug and Drug Products

#### **CHINA**

Date Published: 05/13/2016 Attix Pharmaceuticals (Xiamen) Xiangyue Road, NO. 7 Xinganlu, Shamen, Fujian CHINA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/13/2016 Desc: All Drugs and Drug Products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/13/2016 Notes: All Drugs and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/13/2016 Notes: All Drugs and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products Date Published: 12/20/2016 Ausmetics Daily Chemicals (Guangzhou) Co., Ltd. Economic And Technical, NO. 1 Jinxiulu; Huangpu, Guangzhou, Guangdong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 12/20/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Baoying County Fukang Medical Appliance Co., Ltd. Date Published: 09/20/2016 Guangyang road, Huangcheng, Baoying, Yangzhou, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/20/2016 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/20/2016 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 09/20/2016 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 09/20/2016 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 09/20/2016

Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 09/20/2016 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 09/20/2016 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 09/20/2016 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 09/20/2016 Notes: All Drug and Drug Products Beijing Rimeng Biological Technology Co. Ltd. Date Published: 01/24/2018 No. 6a Tielunan, Daxing, Beijing, Beijing CHINA 53 - - - - Cosmetics Date Published: 01/24/2018 Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/24/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 01/24/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 01/24/2018 Notes: All Drug and Drug Products Beijing Shunxin Meihua Bio-technical Co., Ltd. Date Published: 07/22/2014 No 7 Fuqiandongjie, Shunyi District, Shunyiqu, Beijingshi CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 56 - - - - Antibiotics (Human/Animal) Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 60 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 61 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 62 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 63 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 64 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 65 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection 66 - - - - Human and Animal Drugs Date Published: 07/22/2014 Notes: All drug products; Firm refused FDA inspection Date Published: 04/29/2016 Beijing Taiyang Pharmaceutical Industry Co Ltd No 1 Shuangqiao Xili, Chaoyang, Beijing, Beijing CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/29/2016 Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 04/29/2016 Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 04/29/2016

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

61 - - - -- Human and Animal Drugs

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All drugs and drug products; Problem(s): (GMP) Good Manufacturing Practices

## **Bicooya Cosmetics Limited**

NO 17 Yanhu Lu, Yiwu, Jinhua, Zhejiang CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices

#### **Bluetech Chemicals Limited**

Rm 703, No. 25, Lane 175, Shanghai, CN-31 CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All drug products

56 - - - - Antibiotics (Human/Animal)

Notes: All drug products

60 - - - - Human and Animal Drugs

Notes: All drug products

61 - - - -- Human and Animal Drugs

Notes: All drug products

62 - - - - Human and Animal Drugs

Notes: All drug products

63 - - - - Human and Animal Drugs

Notes: All drug products

64 - - - -- Human and Animal Drugs

Notes: All drug products

65 - - - - Human and Animal Drugs

Notes: All drug products

66 - - - - Human and Animal Drugs

Notes: All drug products

## Boai Xinda Food Co., Ltd.

The North Of Dong Wang He, Xiaojing , Boai, Henansheng CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All drug products

56 - - - - Antibiotics (Human/Animal)

Notes: All drug products

Date Published: 04/29/2016

#### Date Published: 06/29/2017

#### Date Published: 09/17/2010

## Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

60 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products 61 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products 62 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products 63 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products 64 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products 65 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products 66 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All drug products CAO Medical Equipment Co., Ltd. Date Published: 11/26/2018 No. 19 Baihe Street, Langfang Industrial Zone, Langfang, Hebei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/26/2018 Notes: All Drugs 56 - - - - Antibiotics (Human/Animal) Date Published: 11/26/2018 Notes: All Antibiotics 60 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs 61 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs 62 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs 63 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs 64 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs 65 - - - - Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs 66 - - - - Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drugs Date Published: 09/30/2013 Changshu Huagang Pharmaceuticals Co., Ltd Yuxiang Village, Shanghu Town, , Changshu City, Jiangsu Province CHINA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 09/30/2013 Desc: All drug and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/30/2013 Notes: All drug and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/30/2013 Desc: All drug and drug products 60 - - - -- Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products 61 - - - - Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products 62 - - - - Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products 63 - - - - Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products 64 - - - - Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products 65 - - - - Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products 66 - - - - Human and Animal Drugs Date Published: 09/30/2013 Notes: All drug and drug products **Changzhou Anyuan Import & Export** Date Published: 08/11/2017 Fuchen Garden Suite, 1-403; Xinbei District, Changzhou, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/11/2017

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Date Published: 08/11/2017 66 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Changzhou Jintan Qianyao Pharmaceutical Raw Materials Date Published: 05/04/2017 No. 678 Zhuangcheng, Chengzhou, Jintan, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/04/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/04/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/04/2017 Notes: All Drug and Drug Products Changzhou SPL Company, Ltd. Date Published: 09/10/2009 West Rd., Hutang Township, Wujin City, Changzhou City, Jiangsusheng CHINA 55 R - - 75 Crude Heparin (Pharmaceutic Necessity) Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 55 R - - 99 Pharmaceutic Necessities, N.E.C. Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives) Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 61 L - - 08 Heparin Sodium (Anti-Coagulant) Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 61 L - - 22 Anti-Coagulant Heparin Sol Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 61 L - - 30 Heparin Calcium (Anti-Coagulant) Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 80 N - - ZW Heparin Vascular access flush Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 81 J - - BR Test, Heparin Neutralization Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 81 J - - OX Analyzer, Heparin, Automated Date Published: 09/10/2009 Notes: All heparin products 3/10/2008 81 K - - FF Assay, Heparin Date Published: 09/10/2009 Notes: All heparin products 3/10/2008

China Resources Sanjiu Medical and Pharmaceutical Co., Ltd. Date Published: 09/03/2014 Guanlan Hi-Tech Park, NO. 1 Guanging Rd; Longhua District, Shenzhen, Guangdong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/03/2014 Notes: (GMP) Good Manufacturing Practices China Resources Zizhu Pharmaceutical Co., Ltd. Date Published: 03/08/2017 No. 27 Chaoyang Road, Beijing, Beijing CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/08/2017 Notes: All Drugs and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/08/2017 Notes: All Drugs and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products **Chongqing Imperial Bio Chem Co** Date Published: 09/10/2009 5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbeiqu, Zhongqingshi CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: All APIs 3/16/2009 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: All APIs 3/16/2009 60 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 61 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 63 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 64 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 66 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009

Chongging Lummy Pharmaceutical Co. Ltd. Date Published: 04/19/2016 Economic And Technological, NO. 2 the 4th Branch Rd, Huaa?? Nan Road, Chongqing, Changshou District CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 04/19/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Chongging Paiguiang Agribyproduct Co., Ltd Date Published: 09/10/2009 158 Gonglongpo, Yudong, Chongqing, CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: All APIs 3/16/2009 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: All APIs 3/16/2009 60 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 61 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 63 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 64 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 66 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All APIs 3/16/2009 Cixi Zhixin Bird Clean-Care Product Co., Ltd. Date Published: 11/22/2016 NO. 137 Balilu, Cixi, Ningbo, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Fercy Personal Care Products Co., Ltd

An'Wen Industrial, Lane 299 Cangsong Road; Zone Pan County, Jinhua, CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/10/2012

Notes: All Drug Products

56 - - - - Antibiotics (Human/Animal) Date Published: 05/10/2012

Notes: All Drug Products

60 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

61 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

62 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

63 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

64 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

65 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

66 - - - - Human and Animal Drugs Date Published: 05/10/2012

Notes: All Drug Products

## Foshan Flying Medical Products Co., Ltd.

No. 49 Xiangshan 2th Road, Fengtain Industrial District, Foshan, Guangdong CHINA

53 - - - - Cosmetics Date Published: 05/23/2017

Desc: All Drug and Drug Products

Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Date Published: 05/23/2017

Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or

benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

56 - - - - Antibiotics (Human/Animal) Date Published: 05/23/2017

Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

60 - - - - Human and Animal Drugs Date Published: 05/23/2017

Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

61 - - - - Human and Animal Drugs Date Published: 05/23/2017

Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

62 - - - - Human and Animal Drugs

Date Published: 05/23/2017 Notes: All Drug and Drug Products: For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or

benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

63 - - - - Human and Animal Drugs Date Published: 05/23/2017

Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or

benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

64 - - - - Human and Animal Drugs Date Published: 05/23/2017

Notes: All Drug and Drug Products; For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or

benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

65 - - - - Human and Animal Drugs Date Published: 05/23/2017

Notes: All Drug and Drug Products: For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or

benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

66 - - - - Human and Animal Drugs Date Published: 05/23/2017

Notes: All Drug and Drug Products: For Industry Codes 53, 68, 79, and 80, only drug and drug products (i.e. isopropyl alcohol pads or

benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

68 - - - - Animal Devices and Diagnostic Products

Desc: All Drug and Drug Products

Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

79 L - - RR Kit, First Aid Date Published: 05/23/2017

Desc: All Drug and Drug Products

Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic towelettes) are subject to DWPE under this notice.

Date Published: 05/23/2017

Date Published: 05/10/2012

Date Published: 05/23/2017

79 N - - AB Gauze/Sponge, Nonresorbable For External Use

Desc: All Drug and Drug Products

Notes: For Industry Codes 53: 68: 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic

towelettes) are subject to DWPE under this notice.

79 O - - HO First aid kit without drug

Desc: All Drug and Drug Products

Notes: For Industry Codes 53; 68; 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic

towelettes) are subject to DWPE under this notice.

80 L - - KB Pad, alcohol, device disinfectant Date Published: 05/23/2017

Desc: All Drug and Drug Products

Notes: For Industry Codes 53: 68: 79; and 80; only drug and drug products (i.e. isopropyl alcohol pads or benzalkonium chloride antiseptic

towelettes) are subject to DWPE under this notice.

Foshan Jinxiong Technology Co., Ltd. Date Published: 02/14/2018

Shang'an, Danzhao Town, Lijia Development Zone, , Foshan, CHINA

53 J - - -- Personal Cleanliness Date Published: 02/14/2018

Desc: All Drug and Drug Products

Notes: For industry code 53J; only products found to be drug products are subject to DWPE under this listing.

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/14/2018

Notes: All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal) Date Published: 02/14/2018

Notes: All Drug and Drug Products

Date Published: 02/14/2018

60 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 02/14/2018

Notes: All Drug and Drug Products

62 - - - - Human and Animal Drugs Date Published: 02/14/2018

Notes: All Drug and Drug Products

63 - - - - Human and Animal Drugs Date Published: 02/14/2018

Notes: All Drug and Drug Products

64 - - - - Human and Animal Drugs Date Published: 02/14/2018

Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs

Date Published: 02/14/2018 Notes: All Drug and Drug Products

66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

FriendsUnion(Tianjin) enterprises Itd. Date Published: 09/17/2010

Suites 1808-9 Guohua Building, 857 Dagu-, Nan Road, Hexi, Tianjin, China, tianjin, CN-12 CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/17/2010

Notes: All drug products

56 - - - - Antibiotics (Human/Animal) Date Published: 09/17/2010

Notes: All drug products

60 - - - - Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

61 - - - -- Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

62 - - - - Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

63 - - - -- Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

64 - - - - Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

65 - - - - Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

66 - - - -- Human and Animal Drugs Date Published: 09/17/2010

Notes: All drug products

Guangdong Pharmaceutical Factory #1 Date Published: 09/10/2009

91 Fangcun Dadao, Guangzhou, CHINA

61 G - - -- A-Bacterial Pt. II (Not Antibiotic) Date Published: 09/10/2009

Notes: Active Pharmaceutical Ingredients 12/12/1997

Date Published: 05/23/2017

Date Published: 05/23/2017

Date Published: 02/14/2018

61 H - - -- A-Bacterial Pt. III (Not Antibiotic) Date Published: 09/10/2009 Notes: Active Pharmaceutical Ingredients 12/12/1997 Guangdong Zhanjiang Jimin Pharmaceutical Co., Ltd. Date Published: 08/21/2017 NO. 59 Renmin South Road, Zhangjiang, Guangdong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices Guangzhou Baiyunshan Pharmaceutical Co., Ltd. Date Published: 10/25/2017 No. 52 Xiaogang Damalu, Xinshi Street, Baiyun, Guangzhou, Guangdong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Guangzhou Haishi Biological Technology Co., Ltd. Date Published: 03/14/2016 1/F,2/F, Bldq.1, no.3, Songyuan Rd, New Industrial Zone, No.11 She, Xiamao, Guangdong, Guangzhou CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/14/2016 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/14/2016 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/14/2016 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/14/2016 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/14/2016 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/14/2016 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/14/2016 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/14/2016

Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/14/2016 Notes: All Drug and Drug Products Hangzhou Facecare Cosmetics Co., Ltd. Date Published: 09/14/2017 Heda, No. 755 Yinhai Road, Hangzhou, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Hangzhou Guoguang Touring Commodity Co.,Ltd. Date Published: 10/05/2018 Yuhang District, No. 8 Yushun Road; Jingshan Town, Hangzhou, Zhejiang CHINA 53 - - - - Cosmetics Date Published: 10/05/2018 Desc: All Drug and Drug Products Notes: For 53[][][]] and 80L[][RJ; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/05/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/05/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/05/2018 Notes: All Drug and Drug Products 80 L - - RJ Disinfectant, Medical Devices Date Published: 10/05/2018 Desc: All Drug and Drug Products Notes: For 53[[[[[]]] and 80L[[[RJ; only drug and drug products are subject to DWPE under this notice. Hangzhou Karic Commodities Co., Ltd. Date Published: 07/16/2018 West Lake Science And, No 2 Fifth Avenue, Hangzhou, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/16/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 07/16/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 07/16/2018 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 07/16/2018

Notes: All Drug and Drug Products

62 - - - - Human and Animal Drugs Date Published: 07/16/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 07/16/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 07/16/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 07/16/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 07/16/2018 Notes: All Drug and Drug Products Hangzhou SunKing Nonwovens Co., Ltd. Date Published: 12/11/2018 888 Chongchao Road, Yuhang, Hangzhou, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/11/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/11/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/11/2018 Notes: All Drug and Drug Products Hangzhou Zhongbo Industrial Co., Ltd. Date Published: 09/28/2018 Yuhang District, Changle Industrial Zone, Hangzhou, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/28/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products Hebei Yuxing Bio-Engineering Co., Ltd. Date Published: 07/08/2016 Xicheng District, Ningjin County, Xingtai, Hebei CHINA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 07/08/2016 Desc: All Drugs and Drug Products Notes: Problem(s); (GMP) Good Manufacturing Practices; For Product code 54, only drugs and drug products are subject to this Import Alert Date Published: 07/08/2016 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 07/08/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Henan Lihua Pharmaceutical Co., Ltd. Date Published: 03/29/2018 Middle Of Huanghe Street, Anyang, Henan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/29/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/29/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/29/2018 Notes: All Drug and Drug Products Hubei Danao Pharmaceutical Co., Ltd. Date Published: 11/01/2017 Fandan Road, Danjiangkou, Shiyan, Hubei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/01/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 11/01/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 11/01/2017 Notes: All Drug and Drug Products Hubei Goto Healthcare Co., Ltd. Date Published: 01/10/2018 Servo Ind. Park 5th FI, 1 Qilin Road, Xiangfan, Hubei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/10/2018 Notes: All Drug and Drug Products;

56 - - - - Antibiotics (Human/Animal) Date Published: 01/10/2018 Notes: All Drug and Drug Products: Date Published: 01/10/2018 60 - - - - Human and Animal Drugs Notes: All Drug and Drug Products; 61 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products: 62 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products: 63 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products: 64 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products: 65 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products; 66 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products: **Hunan Norchem Pharmaceutical Co. Ltd.** Date Published: 10/18/2017 No. 20 Mengjiangny Avenue, Economic Development Zone, Jin, Hunan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 10/18/2017 Notes: Add Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices **Huzhou Aupower Sanitary Commodity** Date Published: 08/05/2016 339 Jingsan Road, Changxing Dist, Huzhou, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 08/05/2016 Notes: All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drugs; (GMP) Good Manufacturing Practices Jiangmen Nowadays Daily Goods Co., Ltd. Date Published: 06/07/2017 Boyukou Liangde Chong, Jiangmen, Guangdong CHINA 53 - - - - Cosmetics Date Published: 06/07/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 53; 80; & 95; only drug and drug products (i.e. OTC hand sanitizers and wipes) are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/07/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/07/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/07/2017 Notes: All Drug and Drug Products 80 - - - - General Hospital/Personal Use Date Published: 06/07/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 53; 80; & 95; only drug and drug products (i.e. OTC hand sanitizers and wipes) are subject to DWPE under this notice. 95 - - - - Light Emitting Non-Device Products Date Published: 06/07/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 53; 80; & 95; only drug and drug products (i.e. OTC hand sanitizers and wipes) are subject to DWPE under this Jiangsu YongAn Pharmaceutical Co., Ltd Date Published: 11/27/2017 Chuzhou Industrial Park, No. 8 Jing 15th Road, Huaian, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/27/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 11/27/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/27/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 11/27/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 11/27/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 11/27/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/27/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/27/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 11/27/2017

## Jilin Shulan Synthetic Pharmaceutical Co. Ltd.

No. 2066 Peoples Main Road, Shulan, Jilin, Jilin CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products

Date Published: 03/01/2018

Date Published: 03/01/2018

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/01/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Jinan Jinda Pharmaceutical Chemistry Co., Ltd. Date Published: 11/25/2015 No. 6121 Longquan Road, Zhangqui City (Jinan), Shandong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/25/2015 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 11/25/2015 Notes: All Drug and Drug Products **Kunshan Chemicals & Pharmaceutical Factory** Date Published: 09/10/2009 No 242 Kun Tai Road, Kunshan City, Jiangsu, CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: 8/30/2007 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: 8/30/2007 60 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 61 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 63 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 64 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 66 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: 8/30/2007 Lijiang Yinghua Biochemical and Pharmaceutical Co., Ltd. Date Published: 02/08/2018 Industrial Park, Nankou; Gucheng, Lijiang, Yunnan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices

56 Antibiotics (Human/Animal)	Date Published: 02/08/2018
Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices 60 Human and Animal Drugs	Date Published: 02/08/2018
Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices 61 Human and Animal Drugs	Date Published: 02/08/2018
Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices 62 Human and Animal Drugs	Date Published: 02/08/2018
Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices	
63 Human and Animal Drugs Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices	Date Published: 02/08/2018
64 Human and Animal Drugs Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices	Date Published: 02/08/2018
65 Human and Animal Drugs	Date Published: 02/08/2018
Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices 66 Human and Animal Drugs	Date Published: 02/08/2018
Notes: All Drugs and Drug Products : Problem(s): (GMP) Good Manufacturing Practices	
Longbow First Aid Products Manufactory Building F/2 , A3 Guiping Road; Hantian Industrial Park , Foshan, Guangdong CHINA	Date Published : 08/17/2018
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 08/17/2018
Notes: All Drug and Drug Products 56 Antibiotics (Human/Animal)	Date Published: 08/17/2018
Notes: All Drug and Drug Products 60 Human and Animal Drugs	Date Published: 08/17/2018
Notes: All Drug and Drug Products 61 Human and Animal Drugs	Date Published: 08/17/2018
Notes: All Drug and Drug Products 62 Human and Animal Drugs	Date Published: 08/17/2018
Notes: All Drug and Drug Products	
63 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 08/17/2018
64 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 08/17/2018
65 Human and Animal Drugs	Date Published: 08/17/2018
Notes: All Drug and Drug Products 66 Human and Animal Drugs	Date Published: 08/17/2018
Notes: All Drug and Drug Products	
Lumis Global Pharmaceuticals Co. Ltd. Huishang Mansion Unit 305 , 2 Wudayuan Rd Donghu Ntdz , Wuhan, Hubei CHINA	Date Published : 02/15/2017
54 Vit/Min/Prot/Unconv Diet(Human/Animal)	Date Published: 02/15/2017
Notes: All Drug and Drug Products; For Industry Code 54, only drug and drug products are subject to DWPE under 55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 02/15/2017
Notes: All Drug and Drug Products 56 Antibiotics (Human/Animal)	Date Published: 02/15/2017
Notes: All Drug and Drug Products	
60 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 02/15/2017
61 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 02/15/2017
62 Human and Animal Drugs	Date Published: 02/15/2017
Notes: All Drug and Drug Products 63 Human and Animal Drugs	Date Published: 02/15/2017
Notes: All Drug and Drug Products 64 Human and Animal Drugs	Date Published: 02/15/2017
Notes: All Drug and Drug Products 65 Human and Animal Drugs	Date Published: 02/15/2017
Notes: All Drug and Drug Products	
66 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 02/15/2017

Ming Fai Industrial (Shenzhen) Co LTD

Date Published: 12/21/2017

Bainikeng, Pinghu, Ming Fai Industrial Estate, Shenzhen, Guangdong CHINA 53 J - - -- Personal Cleanliness Date Published: 12/21/2017 Desc: All Drug and Drug Products Notes: For industry code 53J; only products found to be drug products are subject to DWPE under this listing. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/21/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/21/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/21/2017 Notes: All Drug and Drug Products NINGBO LONGWELL BABY PRODUCTS CO LTD Date Published: 12/31/2018 Hong Tang, 235 Kaiyuan Road, Ningbo, Zhejiang CHINA 53 I - - 01 Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products) Date Published: 12/31/2018 Notes: 53 / - - 99 Other Oral Hygiene Products, without Fluoride, N.E.C. Date Published: 12/31/2018 Notes: Date Published: 12/31/2018 55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: 56 - - - - Antibiotics (Human/Animal) Date Published: 12/31/2018 Notes: Date Published: 12/31/2018 60 - - - - Human and Animal Drugs Notes: 61 - - - - Human and Animal Drugs Date Published: 12/31/2018 Notes: 62 - - - -- Human and Animal Drugs Date Published: 12/31/2018 Notes: 63 - - - - Human and Animal Drugs Date Published: 12/31/2018 Notes: Date Published: 12/31/2018 64 - - - - Human and Animal Drugs Notes: 65 - - - - Human and Animal Drugs Date Published: 12/31/2018 66 - - - - Human and Animal Drugs Date Published: 12/31/2018 Notes: 76 K - - KO Ring, Teething, Fluid-Filled Date Published: 12/31/2018 Desc: All Drug and Drug Products Notes:

76 M - - EF Ring, Teething, Non-Fluid Filled

Desc: All Drug and Drug Products

Notes:

Nanjing Maohai Biotech Co.

8 Developing Zone, Yaxi Town, Gaochun County, Nanjing Jiangsu Province, CHINA

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)

Desc: Crude Heparin (Pharmaceutical Necessity)

61 L - - 08 Heparin Sodium (Anti-Coagulant)

Desc: Heparin Sodium (Anti-Coagulant)

Nanjing Pharmaceutical Factory Co., Ltd.

9 Fang Shuilu, Liuhe, Nanjing, Jiangsu CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

63 - - - -- Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

Nantong Strip Medical Supply Co Ltd

Building A, 182 Yuelong South Rd, Nantong, Jiangsu CHINA

50 - - - - Color Additiv Food/Drug/Cosmetic

Notes: All Drug Products

53 - - - - Cosmetics

Notes: All Drug Products

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug Products

60 - - - - Human and Animal Drugs

Notes: All Drug Products

61 - - - - Human and Animal Drugs

Notes: All Drug Products

62 - - - - Human and Animal Drugs

Notes: All Drug Products

63 - - - -- Human and Animal Drugs

Notes: All Drug Products

64 - - - - Human and Animal Drugs

Notes: All Drug Products

65 - - - - Human and Animal Drugs

Notes: All Drug Products

66 - - - - Human and Animal Drugs

Notes: All Drug Products

80 - - - - General Hospital/Personal Use

Notes: All Drug Products

NingBo Huize Commodity Co.,Ltd.

14 Lizhou Road, Yuyao, Zhejiang CHINA

53 - - - - Cosmetics

Desc: All Drug and Drug Products

Date Published: 10/18/2011

Date Published: 12/31/2018

Date Published: 10/18/2011

Date Published: 10/18/2011

Date Published: 09/13/2018

Date Published: 03/27/2013

Date Published: 06/13/2019

Date Published: 06/13/2019

Notes: For 53[[[[[[]]] only drug and drug products (i.e. hand sanitizers; lip balms with sunscreen; etc.) are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/13/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/13/2019 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/13/2019 Notes: All Drug and Drug Products Ningbo Pulisi Daily Chemical Products Co., Ltd Date Published: 06/10/2019 Fangjia Road, Xiaocao'E Town, Yuyao City, Zhejiang CHINA 53 E - - -- Hair Preps(Non-Coloring) Date Published: 06/10/2019 Desc: All Drugs and Drug Products Notes: For Product Codes 53E[][][]; 53J[][][]; 53L[][][] and 53Y[][][]; only drug and drug products are subject to DWPE under this notice 53 J - - -- Personal Cleanliness Date Published: 06/10/2019 Desc: All Drugs and Drug Products Notes: For Product Codes 53E[][][]; 53J[][][]; 53L[][][] and 53Y[][][]; only drug and drug products are subject to DWPE under this notice 53 L - - -- Skin Care Prep Date Published: 06/10/2019 Desc: All Drugs and Drug Products Notes: For Product Codes 53E[[][]; 53J[[][]; 53L[[][]] and 53Y[][][]; only drug and drug products are subject to DWPE under this notice Date Published: 06/10/2019 53 Y - - -- Cosmetics and Cosmetic Products, n.e.c. Desc: All Drugs and Drug Products Notes: For Product Codes 53E[][][]; 53J[][][]; 53L[][][] and 53Y[][][]; only drug and drug products are subject to DWPE under this notice 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/10/2019 Notes: All Drugs and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/10/2019 Notes: All Drugs and Drug Products 60 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products 62 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products 63 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products 65 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/10/2019 Notes: All Drugs and Drug Products Ningbo Smart Pharmaceutical Co., Ltd. Date Published: 04/08/2011 Sec. C1, Ningbo Eco. & , Tech. Dev. Zone, Beilun District , Ningbo, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/08/2011 Notes: All Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 04/08/2011 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 04/08/2011 Notes: All Drug Products 61 - - - -- Human and Animal Drugs Date Published: 04/08/2011

Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 04/08/2011 Notes: All Drug Products 63 - - - - Human and Animal Drugs Date Published: 04/08/2011 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 04/08/2011 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 04/08/2011 Notes: All Drug Products 66 - - - - Human and Animal Drugs Date Published: 04/08/2011 Notes: All Drug Products Ningbo Unichem Household Products Co Ltd. Date Published: 03/05/2013 No. 27 Luotuo Jiedao Jiushu Fangnanlu , Zhenhai , Ningbo, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/05/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 03/05/2013 60 - - - - Human and Animal Drugs Date Published: 03/05/2013 61 - - - - Human and Animal Drugs Date Published: 03/05/2013 62 - - - - Human and Animal Drugs Date Published: 03/05/2013 63 - - - - Human and Animal Drugs Date Published: 03/05/2013 64 - - - - Human and Animal Drugs Date Published: 03/05/2013 65 - - - - Human and Animal Drugs Date Published: 03/05/2013 66 - - - - Human and Animal Drugs Date Published: 03/05/2013 Ningbo Zhixin Bird Clean-Care Product Co. Ltd. Date Published: 11/22/2016 137 Bali Road, Zhangqi Town, Zhejang, CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 11/22/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Northeast Pharmaceutical Group Co., Ltd. Date Published: 09/10/2009 37 Zhonggongbeijie, Tiexi, Chenyang, Liaoning CHINA 45 - - - - Food Additives (Human Use) Date Published: 08/28/2010 Notes: All Pharmaceutical Products; \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products.; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE Date Published: 08/28/2010

46 - - - - Food Additives (Human Use)

Notes: All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE Date Published: 08/28/2010

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)

Notes: \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to **DWPE** 

## 55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: 10/30/2007;All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products;NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

56 - - - - Antibiotics (Human/Animal)

Notes: 10/30/2007 All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

60 - - - - Human and Animal Drugs

Notes: 10/30/2007 All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: PRODUCT CODE 60S[[[]26 FOR PRODUCT SUCRALFATE IS EXEMPT FROM THIS ALERT. NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPF

61 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

62 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

63 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

64 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

65 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

66 - - - - Human and Animal Drugs

Notes: 10/30/2007; All Pharmaceutical Products \*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE

#### Nox Bellcow Cosmetics Co. Ltd.

No. 50 Dongfu North Road , Nantou Town , Zhongshan City, Guangdong CHINA

53 L F - 01 Cleansing (Cold Creams, Cleansing Lotions, Liquids, Pads) (Skin Care Preparations), Pads Date Published: 12/27/2017

Desc: Clear Defense Moisturizing Hand Sanitizing Wipes with Ethyl Alcohol

Notes: (GMP) Good Manufacturing Practices; Note; For Product Codes 53LF01 and 53LY01; only drug and drug products are subject to DWPE under this notice

53 L Y - 99 Other Skin Care Preparations, N.E.C., Not Elsewhere Classified (NEC)

Desc: Clear Defense Moisturizing Hand Sanitizing Wipes with Ethyl Alcohol

Notes: (GMP) Good Manufacturing Practices; Note; For Product Codes 53LF01 and 53LY01; only drug and drug products are subject to DWPE under this notice

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices

60 - - - -- Human and Animal Drugs Date Published: 12/27/2017

Date Published: 09/10/2009

Date Published: 12/27/2017

Date Published: 12/27/2017

Date Published: 12/27/2017

Date Published: 12/27/2017

Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drugs and Drug Products: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices Qinhuangdao Zizhu Pharmaceutical, Co. Date Published: 03/08/2017 No 10, Longhai Road, Economic & Technological Development Zon, Qinhuangdao, Hebei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/08/2017 Notes: All Drugs and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/08/2017 Notes: All Drugs and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/08/2017 Notes: All Drugs and Drug Products Shandong Vianor Biotech Co., Ltd. Date Published: 08/22/2017 Innovation Park Unit D, Technology Ave, Linyi, Shandong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 64 - - - -- Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/22/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices Shanghai Biochemial And Pharmaceutical Co Ltd Date Published: 09/10/2009 Room A403, No. 494 Zhongxing Road, Shanghai, CHINA 55 R - - 75 Crude Heparin (Pharmaceutic Necessity) Date Published: 09/10/2009 Notes: All heparin products 1/21/2009 55 R - - 99 Pharmaceutic Necessities, N.E.C. Date Published: 09/10/2009 Notes: All heparin products 1/21/2009

57 D 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)	Date Published: 09/10/2009
Notes: All heparin products 1/21/2009 61 L 08 Heparin Sodium (Anti-Coagulant)	Date Published: 09/10/2009
Notes: All heparin products 1/21/2009 61 L 22 Anti-Coagulant Heparin Sol	Date Published: 09/10/2009
Notes: All heparin products 1/21/2009 61 L 30 Heparin Calcium (Anti-Coagulant)	Date Published: 09/10/2009
Notes: All heparin products 1/21/2009  80 N ZW Heparin Vascular access flush	Date Published: 09/10/2009
Notes: All heparin products 1/21/2009	
81 J BR Test, Heparin Neutralization Notes: All heparin products 1/21/2009	Date Published: 09/10/2009
81 J OX Analyzer, Heparin, Automated Notes: All heparin products 1/21/2009	Date Published: 09/10/2009
81 K FF Assay, Heparin Notes: All heparin products 1/21/2009	Date Published: 09/10/2009
Shanghai Huhui Daily Use Chemical Products Co., Ltd.	Date Published : 04/03/2013
Pudong District , NO 8 Ludalu , Shanghai, Shanghai CHINA	
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 04/03/2013
60 Human and Animal Drugs	Date Published: 04/03/2013
61 Human and Animal Drugs 62 Human and Animal Drugs	Date Published: 04/03/2013 Date Published: 04/03/2013
63 Human and Animal Drugs	Date Published: 04/03/2013
64 Human and Animal Drugs	Date Published: 04/03/2013
65 Human and Animal Drugs	Date Published: 04/03/2013
66 Human and Animal Drugs	Date Published: 04/03/2013
Shanghai Life-Beauty Cosmetics Co., Ltd.	Date Published : 03/28/2014
NO 2000 Fengxianglu , Baoshan , Shanghai, Shanghai CHINA 53 E 06 Shampoos (Hair Preparations, Non-coloring)	Date Published: 03/28/2014
Desc: Dandruff Shampoo	Date Published: 03/20/2014
Notes: (GMP) Good Manufacturing Practices	
53 F 04 Hair Shampoos (Coloring) (Hair Coloring Preparations)	Date Published: 03/28/2014
Desc: Dandruff Shampoo	Bate 1 abilioned: 00/20/2011
Notes: (GMP) Good Manufacturing Practices	
53 J 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C.	Date Published: 03/28/2014
Desc: Hand Sanitizers	
Notes: (GMP) Good Manufacturing Practices	
53 J Personal Cleanliness	Date Published: 03/28/2014
Desc: Antiperspirants	
Notes: (GMP) Good Manufacturing Practices	
53 L 03 Face, Body, and Hand (excluding Shaving Preparations) (Skin Care Preparations)	Date Published: 03/28/2014
Desc: Hand Sanitizers	
Notes: (GMP) Good Manufacturing Practices 55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	Date i ublished. 05/20/2014
60 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	Bate 1 abilioned: 00/20/2011
61 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	
62 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	
63 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	D
64 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices 65 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	Date 1 abilistica. 05/20/2014
66 Human and Animal Drugs	Date Published: 03/28/2014
Notes: All Drugs;(GMP) Good Manufacturing Practices	_ 3.5 . 32554. 00/20/2011

Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd. Date Published: 09/10/2009 387 Shangqiulu, Shanghai, Shanghai CHINA 55 R - - 75 Crude Heparin (Pharmaceutic Necessity) Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 55 R - - 99 Pharmaceutic Necessities, N.E.C. Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives) Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 61 L - - 08 Heparin Sodium (Anti-Coagulant) Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 61 L - - 22 Anti-Coagulant Heparin Sol Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 61 L - - 30 Heparin Calcium (Anti-Coagulant) Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 80 N - - ZW Heparin Vascular access flush Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 81 J - - BR Test. Heparin Neutralization Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 81 J - - OX Analyzer, Heparin, Automated Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 81 K - - FF Assay, Heparin Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd. Date Published: 09/10/2009 1317 Jianchuanlu, Minhang District, Shanghai, Shanghai CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 60 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 61 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 63 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 64 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products 66 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: All API's 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for heparin products

## **Shanghai Weierya Daily Chemicals Factory**

No. 1072 Dongsheng Lu, Shanghai, Shanghai CHINA

53 J - - 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C. Date Published: 09/14/2017

Desc: Hand Sanitizer

Notes: Problem(s); (GMP) Good Manufacturing Practices

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/14/2017

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 09/14/2017 56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 09/14/2017

60 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Shanwei Honghui Daily Appliance Co., Ltd. Date Published: 11/02/2017 Chunzai Garden Wuya Hong, Cao Town, Shanwei, Guangdong CHINA 53 I - - 01 Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products) Date Published: 11/02/2017 Desc: Dentifrices Notes: (GMP) Good Manufacturing Practices; For Product Code 53[][]01; only drug and drug products are subject to DWPE under this notice 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 11/02/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Shenzhen Senton Science & Technology Co.,Ltd. Date Published: 11/21/2017 Longdong Community 294, Longnanlu; Longgang, Shenzhen, Guangdong CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/21/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 11/21/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 11/21/2017 Notes: All Drug and Drug Products Sichuan Emeishan Pharmaceutical Co., Ltd. Date Published: 09/28/2018

High, No. 6 Yingbindadao; Shizhong, Leshan, Sichuan CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/28/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products Sichuan Friendly Pharmaceutical Co., Ltd. Date Published: 03/22/2018 680 Hong Pailu , Dongxing , Neijiang, Sichuan CHINA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 08/23/2018 Notes: All Drug and Drug Products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/22/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/22/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/22/2018 Notes: All Drug and Drug Products 73 - - - - Anesthesiology Date Published: 08/23/2018 Notes: All Drug and Drug Products 74 - - - - Cardiovascular Date Published: 08/23/2018 Notes: All Drug and Drug Products 76 - - - - Dental Date Published: 08/23/2018 Notes: All Drug and Drug Products 77 - - - - Ear, Nose And Throat Date Published: 08/23/2018 Notes: All Drug and Drug Products 78 - - - - Gastroenterological & Urological Date Published: 08/23/2018 Notes: All Drug and Drug Products 79 - - - - General & Plastic Surgery Date Published: 08/23/2018 Notes: All Drug and Drug Products 80 - - - - General Hospital/Personal Use Date Published: 08/23/2018 Notes: All Drug and Drug Products 84 - - - - Neurological Date Published: 08/23/2018 Notes: All Drug and Drug Products 85 - - - - Obstetrical & Gynecological Date Published: 08/23/2018 Notes: All Drug and Drug Products 86 - - - - Ophthalmic Date Published: 08/23/2018 Notes: All Drug and Drug Products 87 - - - - Orthopedic Date Published: 08/23/2018

Notes: All Drug and Drug Products Date Published: 08/23/2018 89 - - - - Physical Medicine Notes: All Drug and Drug Products 90 - - - - Radiological Date Published: 08/23/2018 Notes: All Drug and Drug Products Sichuan Pharmaceutical Co., Ltd. Date Published: 05/08/2012 189 Huayuanlu, Pengzhou, Chengdou, Sichuan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/08/2012 Notes: All drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/08/2012 Notes: All drug products 60 - - - -- Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products 61 - - - -- Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products 62 - - - -- Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products 63 - - - -- Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products 64 - - - - Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products 65 - - - - Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products 66 - - - - Human and Animal Drugs Date Published: 05/08/2012 Notes: All drug products Suzhou No. 4 Pharmaceutical Factory Date Published: 07/10/2014 171 Baiyanglu, Suzhou, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/10/2014 56 - - - - Antibiotics (Human/Animal) Date Published: 07/10/2014 60 - - - - Human and Animal Drugs Date Published: 07/10/2014 61 - - - -- Human and Animal Drugs Date Published: 07/10/2014 62 - - - - Human and Animal Drugs Date Published: 07/10/2014 63 - - - - Human and Animal Drugs Date Published: 07/10/2014 64 - - - - Human and Animal Drugs Date Published: 07/10/2014 65 - - - -- Human and Animal Drugs Date Published: 07/10/2014 66 - - - - Human and Animal Drugs Date Published: 07/10/2014 Suzhou Pharmaceutical Technology Co.,Ltd Date Published: 10/17/2016 Tongjing Commercial Plaza Room 920 # 3, Jiefang Rd, Suzhou, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/17/2016 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/17/2016 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/17/2016 Notes: All Drug and Drug Products Taizhou Kanglin Health Protection Products Co., Ltd. Date Published: 01/15/2013

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54 Vit/Min/Prot/Unconv Diet(Human/Animal) 55 Pharm Necess & Ctnr For Drug/Bio 56 Antibiotics (Human/Animal) 60 Human and Animal Drugs 61 Human and Animal Drugs 62 Human and Animal Drugs 63 Human and Animal Drugs 64 Human and Animal Drugs	Date Published: 01/15/2013
66 Human and Animal Drugs 80 L KB Pad, alcohol, device disinfectant	Date Published: 01/15/2013 Date Published: 01/15/2013
Tianjin Boai Pharmaceutical Co. Ltd	Date Published : 09/17/2010
NO. 4 Ronghua Road , Xiqing , Tianjin, Tianjin CHINA 55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/17/2010
Notes: All drug products 56 Antibiotics (Human/Animal)	Date Published: 09/17/2010
Notes: All drug products 60 Human and Animal Drugs	Date Published: 09/17/2010
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65 Human and Animal Drugs Notes: All drug products	Date Published: 09/17/2010
66 Human and Animal Drugs Notes: All drug products	Date Published: 09/17/2010
Tianjin Boai Pharmaceutical Ltd. co.	Date Published : 09/17/2010
Tianjin Boai Pharmaceutical Ltd. co. 6, Rd Ronghua, Town Nanhe, Dist. Xiqing, Tianjin, Tianjin, CN-12 CHINA 55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/17/2010  Date Published: 09/17/2010
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6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin , CN-12 CHINA  55 Pharm Necess & Ctnr For Drug/Bio Notes: All drug products  56 Antibiotics (Human/Animal) Notes: All drug products  60 Human and Animal Drugs Notes: All drug products  61 Human and Animal Drugs Notes: All drug products  62 Human and Animal Drugs Notes: All drug products  63 Human and Animal Drugs Notes: All drug products  63 Human and Animal Drugs Notes: All drug products	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin , CN-12 CHINA  55 Pharm Necess & Ctnr For Drug/Bio Notes: All drug products  56 Antibiotics (Human/Animal) Notes: All drug products  60 Human and Animal Drugs Notes: All drug products  61 Human and Animal Drugs Notes: All drug products  62 Human and Animal Drugs Notes: All drug products  63 Human and Animal Drugs Notes: All drug products	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin , CN-12 CHINA  55 Pharm Necess & Ctnr For Drug/Bio  Notes: All drug products  56 Antibiotics (Human/Animal)  Notes: All drug products  60 Human and Animal Drugs  Notes: All drug products  61 Human and Animal Drugs  Notes: All drug products  62 Human and Animal Drugs  Notes: All drug products  63 Human and Animal Drugs  Notes: All drug products  64 Human and Animal Drugs  Notes: All drug products  64 Human and Animal Drugs  Notes: All drug products  65 Human and Animal Drugs  Notes: All drug products	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin , CN-12 CHINA  55 Pharm Necess & Ctnr For Drug/Bio Notes: All drug products  56 Antibiotics (Human/Animal) Notes: All drug products  60 Human and Animal Drugs Notes: All drug products  61 Human and Animal Drugs Notes: All drug products  62 Human and Animal Drugs Notes: All drug products  63 Human and Animal Drugs Notes: All drug products  63 Human and Animal Drugs Notes: All drug products  64 Human and Animal Drugs Notes: All drug products	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin , CN-12 CHINA  55 Pharm Necess & Ctnr For Drug/Bio  Notes: All drug products  56 Antibiotics (Human/Animal)  Notes: All drug products  60 Human and Animal Drugs  Notes: All drug products  61 Human and Animal Drugs  Notes: All drug products  62 Human and Animal Drugs  Notes: All drug products  63 Human and Animal Drugs  Notes: All drug products  64 Human and Animal Drugs  Notes: All drug products  65 Human and Animal Drugs  Notes: All drug products  65 Human and Animal Drugs  Notes: All drug products  66 Human and Animal Drugs  Notes: All drug products  66 Human and Animal Drugs  Notes: All drug products	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin, CN-12 CHINA  55 Pharm Necess & Ctnr For Drug/Bio Notes: All drug products  56 Antibiotics (Human/Animal) Notes: All drug products  60 Human and Animal Drugs Notes: All drug products  61 Human and Animal Drugs Notes: All drug products  62 Human and Animal Drugs Notes: All drug products  63 Human and Animal Drugs Notes: All drug products  64 Human and Animal Drugs Notes: All drug products  65 Human and Animal Drugs Notes: All drug products  65 Human and Animal Drugs Notes: All drug products  66 Human and Animal Drugs Notes: All drug products  7 Human and Animal Drugs Notes: All drug products  Tianjin Zhongan Pharmaceutical Co., Ltd.  Xiqing , 188 Fukang Road , Tianjin, Tianjin CHINA  55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin, CN-12 CHINA 55 Pharm Necess & Ctnr For Drug/Bio Notes: All drug products (Human/Animal) Notes: All drug products 60 Human and Animal Drugs Notes: All drug products 61 Human and Animal Drugs Notes: All drug products 62 Human and Animal Drugs Notes: All drug products 62 Human and Animal Drugs Notes: All drug products 63 Human and Animal Drugs Notes: All drug products 64 Human and Animal Drugs Notes: All drug products 65 Human and Animal Drugs Notes: All drug products 65 Human and Animal Drugs Notes: All drug products 65 Human and Animal Drugs Notes: All drug products 65 Human and Animal Drugs Notes: All drug products 7 Iianjin Zhongan Pharmaceutical Co., Ltd. Xiqing , 188 Fukang Road , Tianjin, Tianjin CHINA 55 Pharm Necess & Ctnr For Drug/Bio Notes: Problem: (GMP) Good Manufacturing Practices 56 Antibiotics (Human/Animal)	Date Published: 09/17/2010
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin, CN-12 CHINA 55 Pharm Necess & Ctnr For Drug/Bio Notes: All drug products (Human/Animal) Notes: All drug products (60 Human and Animal Drugs Notes: All drug products (61 Human and Animal Drugs Notes: All drug products (62 Human and Animal Drugs Notes: All drug products (63 Human and Animal Drugs Notes: All drug products (63 Human and Animal Drugs Notes: All drug products (64 Human and Animal Drugs Notes: All drug products (65 Human and Animal Drugs Notes: All drug products (65 Human and Animal Drugs Notes: All drug products (65 Human and Animal Drugs Notes: All drug products (65 Human and Animal Drugs Notes: All drug products (71 Human and Animal Drugs Notes: All drug products (72	Date Published: 09/17/2010

61 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices Wuhan Chinese Moxibustion Technology Dev. Co., Ltd. Date Published: 10/19/2017 Miaoshan Pharmaceutical Industry Park, East Lake High-Tech Dev. Zone, Wuhan, Hubei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/19/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/19/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/19/2017 Notes: All Drug and Drug Products 89 / - - -- Portion of device code Date Published: 10/19/2017 Desc: All Drug and Drug Products Notes: For industry code 89I; only products found to be drug products are subject to DWPE under this listing Xi'an Livingbond Nonwoven Products Corp., Ltd. Date Published: 04/12/2019 No. 3 Standardized Plant, Xingyuan Rd, Fengjing Industrial Park, Hu County, Xian, Shaanxi CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/12/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 04/12/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Date Published: 04/12/2019 Notes: All Drug and Drug Products Xiamen Origin Biotech Co. Ltd. Date Published: 05/13/2016 NO. 7 Xiang Yue Road, Xiamen Torch, Xiamen, Fujian CHINA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/13/2016 Desc: All Drugs and Drug Products

Notes: (GMP) Good Manufacturing Practices

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/13/2016

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products:Problem(s): (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

## Xinxiang Pharmaceutical Co. Ltd.

NO. 30 Jianshe West Road, Beigandao, Henan, CHINA

53 - - - - Cosmetics

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)

Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

60 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice. 61 - - - - Human and Animal Drugs

Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

62 - - - - Human and Animal Drugs Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

63 - - - - Human and Animal Drugs

Date Published: 04/06/2016 Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

64 - - - - Human and Animal Drugs

Date Published: 04/06/2016 Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

65 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

66 - - - - Human and Animal Drugs

Date Published: 04/06/2016 Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all

pharmaceutical intermediates) are subject to DWPE under this notice.

## Xinxiang Tuoxin Biochemical Co. Ltd

Muye And Deyuan Road Cross Street, Xinxiang City, Henan CHINA

53 - - - - Cosmetics Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 04/06/2016

Date Published: 05/13/2016

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Date Published: 04/06/2016

Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

56 - - - - Antibiotics (Human/Animal)

Date Published: 04/06/2016

Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

60 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

61 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

62 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

63 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

64 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

65 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products: Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

66 - - - - Human and Animal Drugs

Date Published: 04/06/2016

Notes: All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.

## Yangzhou Hengyuan Daily Chemical Plastic Co Ltd

Hangji Town, 7 Sitonglu; Hanjiang, Yangzhou, Jiangsu CHINA

53 / - - 01 Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products)

Date Published: 08/12/2016

Date Published: 08/12/2016

Desc: All Drug and Drug Products

Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

53 J - - 02 Deodorants (underarm)(Not Antiperspirant) (Personal Cleanliness)

Date Published: 08/12/2016

Date Published: 08/12/2016

Desc: All Drug and Drug Products

Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

56 - - - - Antibiotics (Human/Animal) Date Published: 08/12/2016

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice

60 - - - - Human and Animal Drugs Date Published: 08/12/2016

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice

Date Published: 08/12/2016 61 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

62 - - - - Human and Animal Drugs Date Published: 08/12/2016

Notes: All Drug and Drug Products: For Industry Code 53: only drug and drug products are subject to DWPE under this notice

63 - - - - Human and Animal Drugs Date Published: 08/12/2016

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice

64 - - - - Human and Animal Drugs Date Published: 08/12/2016

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice

65 - - - - Human and Animal Drugs Date Published: 08/12/2016

Notes: All Drug and Drug Products: For Industry Code 53: only drug and drug products are subject to DWPE under this notice

66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; For Industry Code 53; only drug and drug products are subject to DWPE under this notice

# Yicheng Chemical Corp.

Fuchen Garden Suite, 1-402; Xinbei District, Changzhou, Jiangsu CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

# Date Published: 08/11/2017

Date Published: 08/12/2016

Date Published: 08/11/2017

Date Published: 08/11/2017

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/11/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Yicheng Goto Pharmaceuticals Co., Ltd Date Published: 01/10/2018 Group 1 Gaokeng, Yicheng, Xiangyang, Hubei CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/10/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 01/10/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 01/10/2018 Notes: All Drug and Drug Products Yunnan Hande Bio-Tech. Co. Ltd. Date Published: 05/20/2016 No. 3 Jindingbeilu, Wuhua, Kunming, Yunnan CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/20/2016 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/20/2016 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Date Published: 05/20/2016 Notes: All Drug and Drug Products Zhejiang Bangli Medical Products Co., Ltd Date Published: 09/09/2016 Huachuan Block, 118 South of Yuegui Road, Yongkang City, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal) Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/09/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Zhejiang Casing Animal By-Products Co.,Ltd. Date Published: 10/18/2011 369 Dong Xing Road, Tonglu Economic Developing District, Hangzhou, Zhejiang Province CN-33 CHINA 61 L - - 08 Heparin Sodium (Anti-Coagulant) Date Published: 10/18/2011 Desc: Heparin Sodium (Anti-coagulant) **Zhejiang Huahai Pharmaceutical** Date Published: 09/28/2018 Coastal Industrial Zone, Chuannan No. 1 Branch No. 9, Donghai 5th Avenue, Linhai, Taizhou Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/28/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 09/28/2018 Notes: All Drug and Drug Products Zhejiang Ludao Technology Co., Ltd. Date Published: 12/28/2017 Hairun Street, Taizhou, CHINA 53 D - - -- Fragrance Prep Date Published: 12/28/2017 Desc: All Drug and Drug Products Notes: For industry code 53J; 53D and 53L; only products found to be drug products are subject to DWPE under this listing. 53 J - - -- Personal Cleanliness Date Published: 12/28/2017 Desc: All Drug and Drug Products Notes: For industry code 53J; 53D and 53L; only products found to be drug products are subject to DWPE under this listing. 53 L - - -- Skin Care Prep Date Published: 12/28/2017 Desc: All Drug and Drug Products Notes: For industry code 53J; 53D and 53L; only products found to be drug products are subject to DWPE under this listing. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/28/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/28/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/28/2017 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 12/28/2017 Notes: All Drug and Drug Products

62 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products Date Published: 12/28/2017

Date Published: 11/24/2015

Zhejiang Qianfei Enterprise Co. Ltd.

No 173 Wulian Road , Yiwu , Jinhua, Zhejiang CHINA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

Practices

Date Published: 11/24/2015

# DENMARK

Leo Pharma A/S Date Published : 03/01/2011

Industriparken 55 , Ballerup, DENMARK 61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)

Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.

Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

**Leo Pharmaceutical Products** 

Park Alle 26, Vejen, DENMARK

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)

Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.

Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

Leo Pharmaceutical Products

A 8 , Copenhagen, DENMARK

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)

Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.

Desc: Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

Date Published: 03/01/2011

## **DOMINICAN REPUBLIC**

Labocont Industrial SRL Date Published : 02/08/2018

Entrada Zona Franca, La Caleta, Autopista Las Americas Km. 19, Santo Domingo, DOMINICAN REPUBLIC

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 02/08/2018 Notes: All Drugs and Drug Products: Problem(s): (GMP) Good Manufacturing Practices

#### **FRANCE**

Date Published: 01/17/2018 **BR SAS** 28 Rue De La Procession, Suresnes, FRANCE

53 - - - - Cosmetics

Desc: All Drug and Drug Products

Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice. 56 - - - - Antibiotics (Human/Animal)

Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice. 60 - - - - Human and Animal Drugs Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

61 - - - - Human and Animal Drugs Date Published: 01/17/2018 Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

62 - - - - Human and Animal Drugs Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

Date Published: 01/17/2018 63 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

64 - - - - Human and Animal Drugs Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

65 - - - - Human and Animal Drugs Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

66 - - - - Human and Animal Drugs Date Published: 01/17/2018

Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice.

**CISBIO BIOASSAYS** Date Published: 09/10/2009 1 route du Parc Marcel Boiteux, Codolet, FRANCE

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: Selenomethionine 75 injection

60 - - - - Human and Animal Drugs

Date Published: 09/10/2009 Notes: Selenomethionine 75 injection

61 - - - - Human and Animal Drugs

Notes: Selenomethionine 75 injection 62 - - - - Human and Animal Drugs

Notes: Selenomethionine 75 injection

63 - - - - Human and Animal Drugs Date Published: 09/10/2009

Notes: Selenomethionine 75 injection

64 - - - - Human and Animal Drugs Date Published: 09/10/2009

Notes: Selenomethionine 75 injection

Date Published: 01/17/2018

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 66 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection Date Published: 09/10/2009 Compagnie Oris Industrie Lpib B.P. #2 91 Gif-Sur-Yvette, Saclay, FRANCE 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 60 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 61 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 63 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 64 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 Injection 66 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Selenomethionine 75 injection Ligne St. Barth SAS Date Published: 07/08/2013 Lorient, route de Saline, St Barthelemy, Guadeloupe FRANCE 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/08/2013 60 - - - - Human and Animal Drugs Date Published: 07/08/2013 61 - - - - Human and Animal Drugs Date Published: 07/08/2013 62 - - - - Human and Animal Drugs Date Published: 07/08/2013 63 - - - -- Human and Animal Drugs Date Published: 07/08/2013 64 - - - -- Human and Animal Drugs Date Published: 07/08/2013 65 - - - - Human and Animal Drugs Date Published: 07/08/2013 66 - - - - Human and Animal Drugs Date Published: 07/08/2013 Date Published: 09/10/2009 Societe Chimique Grevis Avenue De La Paix, Limay, FRANCE 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 60 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 61 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 63 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 64 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989 66 - - - -- Human and Animal Drugs Date Published: 09/10/2009 Notes: Sterile bulk pharmaceutical chemicals 8/10/1989

#### **GERMANY**

SANUM-Kehlbeck GmbH & Co. KG Date Published : 07/08/2013

Hasseler Steinweg, 9-12, and Bahnhofstrasse 2-4, Hoya, Niedersachsen GERMANY

50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 07/08/2013 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 07/08/2013 Date Published: 07/08/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio

56 - - - - Antibiotics (Human/Animal) 60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

63 - - - - Human and Animal Drugs 64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

Date Published: 07/08/2013 Date Published: 07/08/2013

Date Published: 07/08/2013

## **GREECE**

CHIA GH LTD. Date Published: 05/06/2013

Ag. Mina 144, Chios, GREECE 55 - - - - Pharm Necess & Ctnr For Drug/Bio

56 - - - - Antibiotics (Human/Animal)

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

63 - - - -- Human and Animal Drugs 64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

Date Published: 05/06/2013 Date Published: 05/06/2013

Date Published: 05/06/2013 Date Published: 05/06/2013 Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013 Date Published: 05/06/2013

Date Published: 05/06/2013

## **HONG KONG**

**CBSCHEM LIMITED** Date Published: 08/31/2013

13th Floor, Nan Fung Industrial City, Tuen Mun, New Territories HONG KONG

35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling Desc: All drugs and drug products

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)

Desc: All drugs and drug products

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Desc: All drugs and drug products

60 - - - - Human and Animal Drugs

Notes: All drugs and drug products

61 - - - - Human and Animal Drugs

Notes: All drugs and drug products

62 - - - - Human and Animal Drugs

Notes: All drugs and drug products

63 - - - - Human and Animal Drugs Notes: All drugs and drug products

64 - - - -- Human and Animal Drugs

Notes: All drugs and drug products

65 - - - - Human and Animal Drugs

Notes: All drugs and drug products 66 - - - - Human and Animal Drugs

Notes: All drugs and drug products

78 - - - - Gastroenterological & Urological

Desc: All drugs and drug products

88 - - - - Pathology

Date Published: 08/31/2013

Desc: All drugs and drug products

**Chan Yat Hing Medicine Factory** Date Published: 12/03/2015 Flat 3, 9/F, Fuk Keung Industrial Bldg., Mong Kok, Kowloon HONG KONG 53 - - - - Cosmetics Date Published: 01/07/2016 Desc: All drug products declared as Cosmetic Products Notes: The firm has a history of importing some of the following drug products under product code 53: Arthritis Pain Relieving Cream, Pain Relieving Balm, Wok Lok Pain Relieving Oil, Shuang Long Pain Relieving Oil, and Red Flower Oil, Pain Relieving Herbal Oil, Pain Relieving Chi Len Oil, Pain Relieving Po Tong Oil, and Back Pain Relieving Oil. This is not an inclusive list; therefore it is recommended that any products offered for import under product code 53 be thoroughly reviewed to determine if said products are drug products and thus subject to DWPE under this listing. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 12/03/2015 Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 12/03/2015 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Luen Wah (HK) Medicine Ltd Date Published: 01/18/2018 412 Room, Paramount Building 406; 12 Ka Yip Street, Chai Wan, Hong Kong Island HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 01/18/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Luen Yick Pharmaceutical Co. Ltd. Date Published: 03/04/2014 Unit B, 7F, Phase 1 Leader Industry Ctr., 188-202 Texaco Rd, Tsuen Wan, Kowloon, HK-NA HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/04/2014 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products

63 - - - -- Human and Animal Drugs

Date Published: 03/04/2014

Import Alert 66-40

7/6/2019

Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products Nan San (HK) Pharmaceutical Factory Ltd. Date Published: 01/08/2018 Hoi Bun Industrial Building, 6 Wing Yip Street, Unit C1, 10/F, Kwun Tong Kowloon, Hong Kong HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/08/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 01/08/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products **Peking Medicine Manufactory** Date Published: 03/04/2014 Unit B, 7/F, Phase 1, Leader Industry Centre, Tsuen Wan, New Territories HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/04/2014 Notes: All Drug Products 60 - - - -- Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 61 - - - -- Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/04/2014 Notes: All Drug Products Date Published: 08/31/2013 Seedings 18 Tin Hau Rd., Room 3, 13/F, Tower 4, Hong Kong, Hong Kong HONG KONG 35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling Date Published: 08/31/2013 Notes: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 08/31/2013 Notes: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/31/2013 Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 08/31/2013 Notes: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products 61 - - - -- Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products

Date Published: 08/31/2013 62 - - - - Human and Animal Drugs Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products 64 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 08/31/2013 Notes: All drugs and drug products 78 - - - - Gastroenterological & Urological Date Published: 08/31/2013 Notes: All drugs and drug products 88 - - - - Pathology Date Published: 08/31/2013 Notes: All drugs and drug products Wong Lap Kwong Medicine Company Limited Date Published: 01/08/2018 Flat B, 4/F, Wah Lung Industrial Building; 49-53 Wang Lung Street, Tsuen Wan, New Territories HONG KONG 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - -- Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

# HUNGARY

Teva Pharmaceutical Works Private Limited Company	Date Published : 05/27/2016
Tancsics Mihaly ut 82, Godollo, Pest HUNGARY	
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
56 Antibiotics (Human/Animal)	Date Published: 05/27/2016
Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices	
60 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
61 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
62 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
63 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
64 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
65 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs;Problem(s): (GMP) Good Manufacturing Practices	
66 Human and Animal Drugs	Date Published: 05/27/2016
Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices	

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

Date Published: 01/08/2018

## **INDIA**

Date Published: 05/05/2014 Aadivighnesh Chem PVT. LTD. A/7 Badrinath Apartment, Simpoli Road, Mumbai, Maharashtra INDIA 56 C - - 66 Ceftazidime (Cephalosporins) Date Published: 05/05/2014 Desc: Ceftazimide for Injection USP (Sterile) **Aarti Drugs Limited** Date Published: 03/23/2015 Plot No. E-22, M.I.D.C., Tarapur, Palghar, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices **Aarti Drugs Ltd** Date Published: 03/23/2015 G-60 Boisar MIDC Tarapur, Tal. Palghar, District Thane, Tarapur, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/23/2015 Notes: All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices Date Published: 08/21/2015 Akorn India PVT 5/2 5/3 Khasra 5/1, Paonta Sahib, Himachal Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/21/2015 Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/21/2015 Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/21/2015 Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/21/2015 Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/21/2015

Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices

Date Published: 08/21/2015 64 - - - - Human and Animal Drugs Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/21/2015 Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/21/2015 Notes: All drugs and drug products Problem: (GMP) Good Manufacturing Practices Date Published: 02/14/2019 **Alchymars ICM SM Private Limited** A - 14 & 20 Sidco Pharmaceutical Complex, Kancheepuram Dist, Alathur, Tamil Nadu INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/14/2019 Notes: All Drugs 56 - - - - Antibiotics (Human/Animal) Date Published: 02/14/2019 Notes: All Antibiotics 60 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs 61 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs 62 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs 63 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs 64 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs 65 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs 66 - - - - Human and Animal Drugs Date Published: 02/14/2019 Notes: All Drugs Amsal Chem Pvt. Ltd. Date Published: 04/11/2013 A-1/401-402-403, GIDC, Ankleshwar, Gujarat, INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/11/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 04/11/2013 60 - - - - Human and Animal Drugs Date Published: 04/11/2013 61 - - - - Human and Animal Drugs Date Published: 04/11/2013 62 - - - - Human and Animal Drugs Date Published: 04/11/2013 63 - - - - Human and Animal Drugs Date Published: 04/11/2013 64 - - - - Human and Animal Drugs Date Published: 04/11/2013 65 - - - - Human and Animal Drugs Date Published: 04/11/2013 66 - - - -- Human and Animal Drugs Date Published: 04/11/2013 **Apotex Research Private Limited** Date Published: 04/12/2018 Plots 1 And 2, Bommasandra Ind. Area, Jigani Link Rd; 4th Phase, Bangalore, Karnataka INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/12/2018 Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 04/12/2018 Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drug and Drug Products; These products are excluded from DWPE: Riluzole tablets (62J[[]16) due to potential drug shortage 63 - - - -- Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Date Published: 04/12/2018 64 - - - - Human and Animal Drugs Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drug and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

**B. JAIN PHARMACEUTICALS PRIVATE LIMITED** Date Published: 01/17/2019 E41/F Riico Ind Area, Khuskara, Rajasthan INDIA 53 L - - 99 Other Skin Care Preparations, N.E.C. Date Published: 01/17/2019 Notes: For Product Codes 53P[][]99 and 53L[][]99; only drug and drug products are subject to DWPE under this notice 53 P - - 99 Other Cosmetic Raw Materials, N.E.C. Date Published: 01/17/2019 Notes: For Product Codes 53P[][]99 and 53L[][]99; only drug and drug products are subject to DWPE under this notice 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/17/2019 56 - - - - Antibiotics (Human/Animal) Date Published: 01/17/2019 Date Published: 01/17/2019 60 - - - - Human and Animal Drugs 61 - - - - Human and Animal Drugs Date Published: 01/17/2019 62 - - - - Human and Animal Drugs Date Published: 01/17/2019 63 - - - - Human and Animal Drugs Date Published: 01/17/2019 64 - - - - Human and Animal Drugs Date Published: 01/17/2019 65 - - - - Human and Animal Drugs Date Published: 01/17/2019 66 - - - - Human and Animal Drugs Date Published: 01/17/2019 **Badrivishal Chemicals & Pharmaceuticals** Date Published: 12/19/2016 Gat No. 29, Village Jambwade (Induri), Post Sudumbre, Taluka Maval, Dist. Pune, INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/19/2016 Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products;(GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 12/19/2016 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices Canton Laboratories Pvt. Ltd. Date Published: 04/10/2014 110 A & B Gidc Estate, Makarpura Road, Vadodara, Gujarat INDIA *54 B - - --* Mineral Date Published: 04/10/2014 Desc: All Drugs and Drug Products Notes: Problem(s) -- (GMP) Good Manufacturing Practices 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; 60 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; 61 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; 62 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; 63 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; 65 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; 66 - - - - Human and Animal Drugs Date Published: 04/10/2014 Notes: All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices; **Centurion Laboratories Private Limited** Date Published: 03/11/2019

P - 2 Tal - Savli , Gidc , Manjusar, Gujarat INDIA 55 - - - -- Pharm Necess & Ctnr For Drug/Bio

Date Published: 03/11/2019

Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/11/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products Contacare Ophthalmics & Diagnostics Date Published: 02/20/2019 310b Village Sim , Block No , Dabhasa, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/20/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 02/20/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 02/20/2019 Notes: All Drug and Drug Products **Emcure Pharmaceuticals Limited** Date Published: 07/13/2015 Plot No. P-1 & P-2, It-Bt Park Phase Ii, Midc, Hinjwadi, Hinjwadi, Pune, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Amikacin inj, antibiotic / 56D[][]06 60 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Prochlorperazine inj, Antiemetic (for nausea/vomiting)/ 61T[][]14 Metoclopramide inj, used for GERD and antiemetic / 61T[][]12 62 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Cidofovir inj, treats eye infection in HIV patients / 62V[][]21 Carmustine inj, cancer / 62I[][]12 63 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 07/13/2015 Notes: All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices

Fleming Laboratories Limited Date Published: 04/11/2011 48 Temple Rock Enclave, Tarbund Road; Plot No; Bhowanpalli, Secunderabad, Telangana INDIA 56 - - - - Antibiotics (Human/Animal) Date Published: 04/11/2011 Notes: All Drug Products 73 - - - - Anesthesiology Date Published: 04/11/2011 Notes: All Drug Products 74 - - - - Cardiovascular Date Published: 04/11/2011 Notes: All Drug Products 76 - - - - Dental Date Published: 04/11/2011 Notes: All Drug Products 77 - - - - Ear, Nose And Throat Date Published: 04/11/2011 Notes: All Drug Products 78 - - - - Gastroenterological & Urological Date Published: 04/11/2011 Notes: All Drug Products 79 - - - - General & Plastic Surgery Date Published: 04/11/2011 Notes: All Drug Products 80 - - - - General Hospital/Personal Use Date Published: 04/11/2011 Notes: All Drug Products 84 - - - Neurological Date Published: 04/11/2011 Notes: All Drug Products 85 - - - - Obstetrical & Gynecological Date Published: 04/11/2011 Notes: All Drug Products 86 - - - - Ophthalmic Date Published: 04/11/2011 Notes: All Drug Products 87 - - - - Orthopedic Date Published: 04/11/2011 Notes: All Drug Products 89 - - - - Physical Medicine Date Published: 04/11/2011 Notes: All Drug Products 90 - - - - Radiological Date Published: 04/11/2011 Notes: All Drug Products Date Published: 10/20/2017 Fleming Laboratories Ltd. Survey No. 270, Kanukunta Road, Nawabpet Village, Medak District, Hyderabad, Telangana Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/20/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/20/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/20/2017 Notes: All Drug and Drug Products **Glint Cosmetics Pvt Ltd** Date Published: 04/17/2019 C 216 - 218 Ttc Industrial Area Midc , T T C Industrial Turbhe D Block Road , Navi Mumbai, Maharashtra INDIA 53 - - - - Cosmetics Date Published: 04/17/2019 **Desc: Cosmetics** Notes: (GMP) Good Manufacturing Practices; For Industry Codes 53; 54 and 55; only drug and drug products are subject to DWPE under this notice 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 04/17/2019 Desc: Vit/Min/Prot/Unconv Diet (Human/Animal)

Notes: (GMP) Good Manufacturing Practices; For Industry Codes 53; 54 and 55; only drug and drug products are subject to DWPE under this

notice

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices; For Industry Codes 53; 54 and 55; only drug and drug products are subject to DWPE under this notice; 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/17/2019 Desc: Pharm Necess & Ctnr For Drug/Bio Notes: (GMP) Good Manufacturing Practices; For Industry Codes 53; 54 and 55; only drug and drug products are subject to DWPE under this notice 56 - - - - Antibiotics (Human/Animal) Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 04/17/2019 Notes: (GMP) Good Manufacturing Practices Goran Pharma Pvt Ltd Date Published: 03/05/2018 Gdic-I, Bhavnagar Road, Sihor, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/05/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices **Health Biotech Limited** Date Published: 04/03/2018 District Solan, Nalgarh Road, Baddi, Himachal Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 04/03/2018

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Date Published: 04/03/2018 **Health Biotech Limited** S.C.O. 162-164, Indian Airlines Building, Top Floor, Sector 34-A, Chandigarh, Punjab INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 04/03/2018 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Hospira Healthcare India Pvt. Ltd. Date Published: 08/01/2018 B11 - B18 B21 - B23 B - 31 - 33 Plots B3 - B6 , Sriperumbudur, Tamil Nadu INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/01/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 08/01/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products **Ipca Laboratories LTd** Date Published: 03/24/2015 1 Pharma Zone, Pithampur, Madhya Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices **Ipca Laboratories Limited** Date Published: 01/22/2015 Village Sejavta, Ratlam, Madhya Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; 56 - - - - Antibiotics (Human/Animal) Date Published: 01/22/2015 Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; This product is excluded from DWPE: Chloroquine Phosphate API/61A[[[]06 62 - - - - Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; 63 - - - - Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from DWPE: Furosemide/64BQS24 65 - - - - Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 66 - - - -- Human and Animal Drugs Date Published: 01/22/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices **Ipca Laboratories Limited** Date Published: 03/24/2015 Plot No. 65 And 99, Danudyog, Ind. Estate, Piparia, Silvasa (D And Nh), INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/24/2015 Notes: All Drugs; GMP) Good Manufacturing Practices; 60 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs;(GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices; 64 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs;(GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/24/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices Date Published: 06/11/2018 JT Cosmetics & Chemicals Pvt Ltd. 53 Kalol Gidc Estate, Panchmahal, Gujarat INDIA 53 - - - - Cosmetics Date Published: 06/11/2018 Desc: All Drug and Drug Products Notes: For industry code 53; only products found to be drug products are subject to DWPE under this listing. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/11/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/11/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 06/11/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/11/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 06/11/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 06/11/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/11/2018

Notes: All Drug and Drug Products

65 - - - - Human and Animal Drugs Date Published: 06/11/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/11/2018 Notes: All Drug and Drug Products Date Published: 07/10/2013 Kamud Drugs Pvt. Ltd. N-6 & 8 MIDC, Kupwad , Taluka Miraj , Sangli, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 07/10/2013 Notes: All drug and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 07/10/2013 Notes: All drug and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/10/2013 Notes: All drug and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 07/10/2013 Notes: All drug and drug products 60 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 61 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 62 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 63 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 64 - - - -- Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 65 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 66 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products Kim Chemicals Private Ltd. Date Published: 08/21/2017 Plot No. G-13/16, Midc, Taloja, Taloja, Raigad, Maharashtra INDIA 53 - - - - Cosmetics Date Published: 08/21/2017 Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products (i.e. petroleum jelly; etc.) are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/21/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 08/21/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products 65 - - - -- Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 08/21/2017 Notes: All Drug and Drug Products Konduskar Laboratories Pvt Ltd Date Published: 07/10/2013 T-47 Kagel Hatkanangale Five Star, MIDC, Talandage (Village), Tal Kagal, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 07/10/2013 Desc: All drug and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 07/10/2013 Desc: All drug and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/10/2013 Notes: All drug and drug products

56 - - - - Antibiotics (Human/Animal) Date Published: 07/10/2013 Desc: All drug and drug products 60 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 61 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 62 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 63 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 64 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 65 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products 66 - - - - Human and Animal Drugs Date Published: 07/10/2013 Notes: All drug and drug products Kopalle Pharma Chemical Pvt Ltd. Date Published: 06/22/2018 Phase Iii, Jd Midla, Hyderabad, Andhra Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/22/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/22/2018 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/22/2018 Notes: All Drug and Drug Products **Lantech Pharmaceuticals Limited** Date Published: 06/27/2019 79 80 & 145 Sy No 78, Chittivalasa, Andhra Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/27/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/27/2019 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/27/2019 Notes: All Drug and Drug Products **Mahendra Chemicals** Date Published: 08/25/2017

B - 1 217 218 2 G I D C Estate, Ahmedabad, Gujarat INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Date Published: 08/25/2017

Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices Date Published: 08/25/2017 56 - - - - Antibiotics (Human/Animal) Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs: All Antibiotics: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/25/2017 Notes: All Drugs; All Antibiotics; (GMP) Good Manufacturing Practices Malladi Drugs & Pharmaceuticals Ltd. Date Published: 12/13/2017 Plot 67, 68, Sipcot Industrial Complex, Vellore, Ranipet, Tamil Nadu INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/13/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/13/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/13/2017 Notes: All Drug and Drug Products Marck Biosciences Ltd. Date Published: 03/12/2014 Plot No. 876, N.H. - 8, Vill: Hariyala, Tal: Matar, Kheda, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/12/2014 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products 63 - - - -- Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products 66 - - - -- Human and Animal Drugs Date Published: 03/12/2014 Notes: All Drug Products Megafine Pharma (P) Limited Date Published: 10/14/2015 48 - 51/201 Plot No 31 - 35, Lakhamapur, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/14/2015 Notes: All Drug and Drug Products

60 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/14/2015 Notes: All Drug and Drug Products Nivedita Chemicals P ITd Date Published: 11/23/2011 A14 MIDC Andheri East, Mumbai, IN-MH INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 60 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic) Date Published: 11/23/2011 Desc: Chlorpheniramine maleate 61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Date Published: 11/23/2011 Desc: Chlorpheniramine maleate 61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Date Published: 11/23/2011 Desc: Pyrilamine maleate Pyrilamine maleate USP 61 X - - 99 Anti-Histaminic N.E.C. Date Published: 11/23/2011 Desc: Pyrilamine maleate Pyrilamine maleate USP 61 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 62 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 63 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 64 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 65 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 66 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate Nivedita Chemicals Pvt. Ltd. Date Published: 11/23/2011 A - 14 Maharashtra , M i d C; Andheri East , Mumbai, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 60 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic) Date Published: 11/23/2011 Desc: Chlorpheniramine maleate 61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Date Published: 11/23/2011 Desc: Pyrilamine maleate Pyrilamine maleate USP 61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Date Published: 11/23/2011 Desc: Chlorpheniramine maleate 61 X - - 99 Anti-Histaminic N.E.C. Date Published: 11/23/2011 Desc: Pyrilamine maleate Pyrilamine maleate USP 61 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 62 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 63 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate

64 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 65 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate 66 - - - - Human and Animal Drugs Date Published: 11/23/2011 Notes: Chlorpheniramine maleate **Pan Drugs Limited** Date Published: 12/08/2015 192 G I D C Makarpura Industrial Estate, M I Estate, Vadodara, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 12/08/2015 Notes: All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 12/08/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices Pan Drugs Ltd. Date Published: 05/05/2015 167-168, GIDC Nandesari Ind. Estate, Nandesari, Vadodara, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 05/05/2015 Notes: All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs;(GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 05/05/2015 Notes: All Drugs; (GMP) Good Manufacturing Practices Polydrug Laboratories Pvt. Ltd. Date Published: 09/11/2015 Plot N37, Ambernath Industrial Area, Anand Nagar MIDC, Mumbai, Maharashtra INDIA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 09/11/2015 Desc: All Drugs Notes: Problem(s): (GMP) Good Manufacturing Practices 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/11/2015 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices **RPG Life Sciences Limited** Date Published: 06/10/2013 25, M.I.D.C. Land, Thane-Belapur Road, Thane, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/10/2013 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/10/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 06/10/2013 60 - - - - Human and Animal Drugs Date Published: 06/10/2013 61 - - - - Human and Animal Drugs Date Published: 06/10/2013 62 - - - - Human and Animal Drugs Date Published: 06/10/2013 63 - - - - Human and Animal Drugs Date Published: 06/10/2013 64 - - - - Human and Animal Drugs Date Published: 06/10/2013 65 - - - - Human and Animal Drugs Date Published: 06/10/2013 Date Published: 06/10/2013 66 - - - - Human and Animal Drugs **RPG Life Sciences Limited** Date Published: 06/11/2013 3102/A G.I.D.C. Estate, 393002, Ankleshwar, Gujarat INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/11/2013 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/11/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 06/11/2013 60 - - - - Human and Animal Drugs Date Published: 06/11/2013 61 - - - - Human and Animal Drugs Date Published: 06/11/2013 62 - - - - Human and Animal Drugs Date Published: 06/11/2013 63 - - - -- Human and Animal Drugs Date Published: 06/11/2013 64 - - - - Human and Animal Drugs Date Published: 06/11/2013 65 - - - - Human and Animal Drugs Date Published: 06/11/2013 66 - - - - Human and Animal Drugs Date Published: 06/11/2013 Date Published: 03/30/2018 Reine Lifescience Plot No-5901, B H Sajjan India Limited, GIDC Industrial Estate, Dist. Bharuch, Ankleshwar, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 56 - - - - Antibiotics (Human/Animal) Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 60 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 61 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 62 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 63 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 64 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 65 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) 66 - - - - Human and Animal Drugs Date Published: 03/30/2018 Notes: All Drug and Drug Products; Good Manufacturing Practices (GMP) Date Published: 05/22/2019 **Rxhomeo Private Limited** 4 - 1 - 424 To 426 Bank Street, Hyderabad, Telangana INDIA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 05/22/2019 Desc: All Drug and Drug Products Notes: For 54nnn; only drug and drug products (i.e. homeopathic products) are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Date Published: 05/22/2019

Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/22/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/22/2019 Notes: All Drug and Drug Products Date Published: 02/15/2017 Sal Pharma 1-7-176 Bakaram, Hyderabad, Andhra Pradesh INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Sentiss Pharma Pvt. Ltd. Date Published: 06/20/2013 Village Khera Nihla, Tehsil Nalargarh, District Solan, Himachal Pradesh INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/20/2013 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/20/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 06/20/2013 60 - - - - Human and Animal Drugs Date Published: 06/20/2013 61 - - - - Human and Animal Drugs Date Published: 06/20/2013 62 - - - - Human and Animal Drugs Date Published: 06/20/2013 63 - - - - Human and Animal Drugs Date Published: 06/20/2013 64 - - - - Human and Animal Drugs Date Published: 06/20/2013 Date Published: 06/20/2013 65 - - - - Human and Animal Drugs 66 - - - - Human and Animal Drugs Date Published: 06/20/2013 86 - - - - Ophthalmic Date Published: 06/20/2013 Smruthi Organics Limited Date Published: 06/03/2013 Plot No. A-27, MIDC, Chincholi, Solapur District, Maharashtra, Maharashtra State INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/03/2013 60 - - - - Human and Animal Drugs Date Published: 06/03/2013 61 - - - - Human and Animal Drugs Date Published: 06/03/2013 62 - - - - Human and Animal Drugs Date Published: 06/03/2013 63 - - - -- Human and Animal Drugs Date Published: 06/03/2013 64 - - - - Human and Animal Drugs Date Published: 06/03/2013 65 - - - - Human and Animal Drugs Date Published: 06/03/2013

66 - - - - Human and Animal Drugs Date Published: 06/03/2013 Sri Krishna Pharmaceuticals Ltd. - Unit II Date Published: 08/13/2015 A-35, Ida, Nacharam, Hyderabad, Andhra Pradesh, INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/13/2015 Notes: All Drugs 60 - - - -- Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs 61 - - - -- Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs 62 - - - - Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs 63 - - - -- Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs 64 - - - - Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs 65 - - - - Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs; This product is excluded from dwpe: Sodium Phenylbutyrate granules/65C[[[]09 66 - - - - Human and Animal Drugs Date Published: 08/13/2015 Notes: All Drugs Srikem Laboratories Pvt. Ltd. Date Published: 07/06/2016 Plot No. 17/24, Midc Taloja, Navi Mumbai, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 07/06/2016 Notes: All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices Stericon Pharma Pvt. Ltd. Date Published: 01/13/2011 No. 9, Sub Layout Of Plot 9, 1st Phase Bommasandra Ind. Area, Bangalore, Karnataka INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/13/2011 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products 61 - - - -- Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products 63 - - - -- Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products 66 - - - -- Human and Animal Drugs Date Published: 01/13/2011 Notes: All Drug Products Sun Pharmaceutical Industries (prev. Ranbaxy) Date Published: 09/10/2009

Village Ganguwala , Tehsil-Paonta Sahib , Sirmaur, Himachal Pradesh INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/10/2009

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

DIOP II entries of Gariciciovii API of linished dosage forms are offered

60 - - - - Human and Animal Drugs Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

62 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

63 - - - -- Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

64 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

65 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

## Sun Pharmaceutical Industries (prev. Ranbaxy)

3 Industrial Area, Dewas, Madhya Pradesh INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

**Date Published : 09/10/2009**Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

60 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

62 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

63 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

64 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

65 - - - -- Human and Animal Drugs

Date Published: 09/10/2009

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Date Published: 03/12/2014

Notes: All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contat DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

# Sun Pharmaceutical Industries Limited - Karkhadi

Plot No. 817/A, Village - Karkhadi , Taluka - Padra District , Vadodara, Gujarat, INDIA

60 - - - -- Human and Animal Drugs Date Published: 03/12/2014

Desc: All Human Drug Products 61 - - - -- Human and Animal Drugs Date Published: 03/12/2014 Desc: All Human Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/12/2014 Desc: All Human Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/12/2014 Desc: All Human Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/12/2014 Desc: All Human Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/12/2014 Desc: All Human Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/12/2014 Desc: All Human Drug Products **Unique Chemicals** Date Published: 06/28/2013 Shiv Mahape Gansoli, Thane Belapur Road, Navi Mumbai, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/28/2013 Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/28/2013 Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/28/2013 Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 61 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 64 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products Vignesh Life Science Pvt Ltd Date Published: 06/28/2013 202 Sarada Residency, H - 26, Madhura Nagar Ameerpet, Hyderabad, Tamil Nadu INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/28/2013 Desc: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 06/28/2013 Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/28/2013 Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/28/2013 Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 61 - - - -- Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 63 - - - -- Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 64 - - - -- Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 06/28/2013

Notes: All drugs and drug products

Vignesh Life Sciences Pvt., Ltd. Date Published: 06/28/2013 93 & 94 P Mundargi Industrial Estate, Bellary Karnataka, INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 06/28/2013 Desc: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 06/28/2013 Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/28/2013 Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 06/28/2013 Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 61 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 64 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 06/28/2013 Notes: All drugs and drug products Vikshara Trading & Investments Ltd. Date Published: 02/08/2017 Odhav Road, Ahmedabad, Gujarat INDIA 53 - - - - Cosmetics Date Published: 02/08/2017 Notes: All Drug and Drug Products; For Industry Code 53, only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/08/2017 Notes: All Drug and Drug Products;. 56 - - - - Antibiotics (Human/Animal) Date Published: 02/08/2017 Notes: All Drug and Drug Products;. 60 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products; 61 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products; 62 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products; 63 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products; 64 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products; 65 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products;. 66 - - - - Human and Animal Drugs Date Published: 02/08/2017 Notes: All Drug and Drug Products; Vipor Chemicals Private Ltd. Date Published: 07/11/2018 218 Gidc Industrial Estate, Vadodara, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/11/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 07/11/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products

64 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products Date Published: 07/11/2018 Vipor Chemicals Private Ltd. 301 Ivory terrace, RC Dutt Road, Vadodara, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/11/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 07/11/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 07/11/2018 Notes: All Drug and Drug Products Vista Pharmaceuticals Limited Date Published: 05/22/2018 Apiic Industrial Estate, Gopalaipalli Village, Nalgonda District, Telangana INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/22/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/22/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/22/2018 Notes: All Drug and Drug Products Vital Laboratories Pvt Ltd Date Published: 05/07/2019 2nd Floor Plot No 48 Service Lane, Mumbai, INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/07/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/07/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 05/07/2019

Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products Vital Laboratories Pvt Ltd Plant I Date Published: 05/07/2019 GIDC Estate, Plots 1416-19 & 1420, 1507/1 & 1507/2, 1601/1 & 1601/2, Vapi, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/07/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/07/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products Vital Laboratories Pvt Ltd Plant II Date Published: 05/07/2019 Plot 1710 & A1 2208, Phase III GIDC, Vapi, Gujarat INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/07/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/07/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products Vital Laboratories Pvt. Ltd. Date Published: 05/07/2019 Venkatesh, Mahant Road Extn. Uttkarsh, , Vile Parle (East), INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/07/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/07/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products

63 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/07/2019 Notes: All Drug and Drug Products **Wockhardt Limited** Date Published: 11/26/2013 L-1, MIDC Area, Jalgaon Road 43, Chikalthana, Aurangabad, Maharashtra INDIA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 09/28/2016 Desc: All Drug and Drug Products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/26/2013 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2016 Desc: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products; \* Notes: These products are excluded from DWPE: Enalapril Maleate (Antihypertensive - part II) (620CA28, 620CS28) 63 - - - -- Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 11/26/2013 Notes: All Drug and Drug Products **Wockhardt Limited** Date Published: 05/22/2013 H - 14/2 Plot , Biotech Park , Karodi, Maharashtra INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/22/2013 Notes: All Drugs and drug products; 56 - - - - Antibiotics (Human/Animal) Date Published: 05/22/2013 Notes: All Drugs and drug products; 60 - - - - Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products; 61 - - - - Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products; 62 - - - - Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products Except -- Enalapril Maleate (620[][]28) 63 - - - -- Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products; 64 - - - - Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products 65 - - - -- Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 05/22/2013 Notes: All Drugs and drug products; Wockhardt, Ltd. Date Published: 08/05/2016 Plot 138 GIDC Industrial, Bulk Drug Division, Dist. Bharuch, Ankleshwar, INDIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/05/2016 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 08/05/2016 Notes: All Drug and Drug Products; 60 - - - - Human and Animal Drugs Date Published: 08/05/2016 Notes: All Drug and Drug Products

61 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 62 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products Notes: All Drug and Drug Products

Yag Mag Labs Private Limited

Survey No. 10, Gaddapotharam Village , Jinnaram Mandal , Medak District, Telangana INDIA

60 L - - 69 Tramadol HCl (Analgesic)

Desc: Tramadol HCl (Analgesic)
60 L - - 99 Analgesic, N.E.C.
Desc: Tramadol HCl (Analgesic)
64 H - - 02 Guaifenesin (Expectorant)
Desc: Guaifensein (Expectorant)

Date Published: 08/05/2016

Date Published: 09/13/2011

Date Published: 09/13/2011

Date Published: 09/13/2011

Date Published: 09/13/2011

Date Published: 02/22/2018

## **IRELAND**

Europharma Concepts Limited
Kilbeggan Road, Clara, Tullamore, County Offaly IRELAND
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
56 - - - - Antibiotics (Human/Animal)
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
60 - - - - Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
61 - - - Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
62 - - - Human and Animal Drugs
Notes: All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
63 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

65 - - - -- Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

ITALY

BBCOS srl

Via Del Lavoro 37, Cherasco, Cuneo ITALY 55 - - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products 56 - - - - - Antibiotics (Human/Animal) Notes: All Drug and Drug Products 60 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 11/27/2017

Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 100 Notes: All Drug and Drug Products 100 Notes: All Drug and Drug Products 100 Notes: All Drug and Drug Products

Topchem SRL

Viale Andrea Doria 17, Milano, MI ITALY 55 - - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All bulk drugs 8/4/1992

56 - - - - - Antibiotics (Human/Animal)
Notes: All bulk drugs 8/4/1992
60 - - - - - Human and Animal Drugs
Notes: All bulk drugs 8/4/1992
61 - - - - - Human and Animal Drugs
Notes: All bulk drugs 8/4/1992
62 - - - - - Human and Animal Drugs
Notes: All bulk drugs 8/4/1992
Notes: All bulk drugs 8/4/1992

63 - - - - - Human and Animal Drugs Notes: All bulk drugs 8/4/1992 64 - - - - - Human and Animal Drugs Notes: All bulk drugs 8/4/1992 65 - - - - - Human and Animal Drugs

Notes: All bulk drugs 8/4/1992 66 - - - - - Human and Animal Drugs Notes: All bulk drugs 8/4/1992 Date Published: 11/27/2017

Date Published: 09/10/2009

## **JAMAICA**

P.A. Benjamin Manufacturing Company Limited

95-97 East Street , Kingston, JM-01 JAMAICA 55 - - - - Pharm Necess & Ctnr For Drug/Bio

60 - - - - Human and Animal Drugs

61 - - - -- Human and Animal Drugs 62 - - - -- Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - -- Human and Animal Drugs 65 - - - -- Human and Animal Drugs

66 - - - - Human and Animal Drugs

Date Published: 08/29/2012

Date Published: 08/29/2012 Date Published: 08/29/2012 Date Published: 08/29/2012 Date Published: 08/29/2012 Date Published: 08/29/2012 Date Published: 08/29/2012

Date Published: 08/29/2012 Date Published: 08/29/2012

**JAPAN** 

Asada Milling Co., Ltd.

253, Oazaobata; Kanra-Machi, Kanra-Gun, Gunma JAPAN

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs Products

60 - - - - Human and Animal Drugs

Notes: All Drugs Products

61 - - - - Human and Animal Drugs

Notes: All Drugs Products

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

Date Published: 02/13/2013

62 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 63 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 64 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 65 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products 66 - - - - Human and Animal Drugs Date Published: 02/13/2013 Notes: All Drugs Products Daito Kasei Kogyo Co Ltd Date Published: 10/25/2017 441, Kidani, Bizen, Okayama JAPAN 53 - - - - Cosmetics Date Published: 10/25/2017 **Desc: Cosmetics** Notes: Problem(s); (GMP) Good Manufacturing Practices; For Industry Code 53; only drug and drug products are subject to DWPE under this 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 10/25/2017 Notes: Cosmetics; Problem(s): (GMP) Good Manufacturing Practices Kanebo Cosmetics Inc. Date Published: 05/06/2013 Odawara-shi Kanagawa 28, Kotobuki-Cho, Odawara, Kanagawa JAPAN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/06/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 05/06/2013 60 - - - - Human and Animal Drugs Date Published: 05/06/2013 61 - - - - Human and Animal Drugs Date Published: 05/06/2013 62 - - - - Human and Animal Drugs Date Published: 05/06/2013 63 - - - - Human and Animal Drugs Date Published: 05/06/2013 64 - - - - Human and Animal Drugs Date Published: 05/06/2013 65 - - - - Human and Animal Drugs Date Published: 05/06/2013 66 - - - - Human and Animal Drugs Date Published: 05/06/2013

# KOREA, REPUBLIC OF (SOUTH)

Amaros Co., Ltd

560 Dunchondae-Ro; Jungwon , Seongnam, Gyeonggi KOREA, REPUBLIC OF (SOUTH)

53 - - - - Cosmetics

Date Published: 08/23/2017

Desc: All Drug and Drug Products

Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/23/2017

Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal)

56 - - - -- Antibiotics (Human/Animal)

Date Published: 08/23/2017

Notes: All Drug and Drug Products

60 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drug and Drug Products Barox Co., Ltd. Date Published: 11/08/2018 Jungwon , Hallasigma 545 Dunchon-Daero , Seongnam, Gyeonggi KOREA, REPUBLIC OF (SOUTH) 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/08/2018 Notes: All Drugs 56 - - - - Antibiotics (Human/Animal) Date Published: 11/08/2018 Notes: All Antibiotics 60 - - - -- Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs 61 - - - - Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs 62 - - - -- Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs 63 - - - -- Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs 64 - - - -- Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs 65 - - - - Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs 66 - - - - Human and Animal Drugs Date Published: 11/08/2018 Notes: All Drugs Cosmecca Korea Co., Ltd. Date Published: 01/08/2018 17-12 Daegeumro196beon-Gil, Daeso-Myeon, Eumseong-Gun, Cungceongbug-do KOREA, REPUBLIC OF (SOUTH) 53 - - - - Cosmetics Date Published: 01/08/2018 Desc: All Drug and Drug Products Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/08/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 01/08/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 65 - - - -- Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products Date Published: 05/11/2017 Firson Co., Ltd.

Seobuk-Gu , 47 Handeul 1-ro , Seobuk-gu, Cheonan-si, Chungcheongnam-do KOREA, REPUBLIC OF (SOUTH)

53 - - - - Cosmetics Date Published: 05/11/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 53 & 77; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/11/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/11/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/11/2017 Notes: All Drug and Drug Products 77 - - - - Ear, Nose And Throat Date Published: 05/11/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 53 & 77; only drug and drug products are subject to DWPE under this notice. Hanbul Cosmetics Co., Ltd Date Published: 03/08/2018 62 Daeseongro547beon-Gil, Samseong-myeon, Eumseong-gun, Cungceongbug-do KOREA, REPUBLIC OF (SOUTH) 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/08/2018 Notes: All Drug and Drug Products; (GMP) Good Manufacturing Practices Hanlim Pharm Co., Ltd. Date Published: 05/03/2018 2-27 Yeongmun-ro, Yonginsi Ceoin-gu, Gyeonggi-do KOREA, REPUBLIC OF (SOUTH) 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 05/03/2018 Notes: All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 05/03/2018 Notes: All Drugs; (GMP) Good Manufacturing Practices Date Published: 09/04/2013 K J I Industrial Co., Ltd. 29 Gyeseok-ro, Dong-myeon, Yangsan-si, Gyeongsangnam-do, KOREA, REPUBLIC OF (SOUTH) 53 - - - - Cosmetics Date Published: 09/04/2013 Desc: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 09/04/2013 Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/04/2013 Notes: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 61 - - - - Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 63 - - - -- Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 64 - - - - Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 65 - - - -- Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 09/04/2013 Notes: All drugs and drug products 80 - - - - General Hospital/Personal Use Date Published: 09/06/2013 Desc: All Drugs and Drug Products 81 - - - -- Hematology Date Published: 09/04/2013 Desc: All drugs and drug products 89 - - - - Physical Medicine Date Published: 09/04/2013 Desc: All drugs and drug products LG Chem., Ltd. Date Published: 05/06/2013 129 Seogam-Ro, Iksan, Jeonrabuk KOREA, REPUBLIC OF (SOUTH) 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 05/06/2013 53 - - - - Cosmetics Date Published: 05/06/2013 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/06/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 05/06/2013 60 - - - - Human and Animal Drugs Date Published: 05/06/2013 61 - - - - Human and Animal Drugs Date Published: 05/06/2013 62 - - - - Human and Animal Drugs Date Published: 05/06/2013 63 - - - - Human and Animal Drugs Date Published: 05/06/2013 64 - - - -- Human and Animal Drugs Date Published: 05/06/2013 65 - - - - Human and Animal Drugs Date Published: 05/06/2013 66 - - - - Human and Animal Drugs Date Published: 05/06/2013 80 - - - - General Hospital/Personal Use Date Published: 05/06/2013 Nature & Nature Co., Ltd. Date Published: 10/31/2018 4th Floor, 735 Yeongdongdae-Ro, Gangnam, Seoul KOREA, REPUBLIC OF (SOUTH) 53 - - - - Cosmetics Date Published: 10/31/2018 Notes: All Drug and Drug Products; For 53[][][][]; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/31/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/31/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 10/31/2018 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 10/31/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 10/31/2018

Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 10/31/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 10/31/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 10/31/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 10/31/2018 Notes: All Drug and Drug Products Date Published: 12/27/2017 **Nowcos Co Ltd** 53714 Segyo Dong, Pyeongtaek, KOREA, REPUBLIC OF (SOUTH) 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 53 - - - - Cosmetics Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/27/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/27/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products Date Published: 12/27/2017 Nowcos Co., Ltd 339-853 Jeon Ui Local Industrial Zo0sin, Yeon Gi-gun Chung Nam, KOREA, REPUBLIC OF (SOUTH) 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 53 - - - - Cosmetics Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/27/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/27/2017 Notes: All Drug and Drug Products 60 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 12/27/2017

Notes: All Drug and Drug Products

Nowcos Co., Ltd Date Published: 12/27/2017 220 Sandan-Gil, Jeonui-Myeon, Sejong, Sejong KOREA, REPUBLIC OF (SOUTH) 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53, only drug and drug products are subject to DWPE under this notice. 53 - - - - Cosmetics Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53, only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/27/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/27/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products Nowcos Co., Ltd. Date Published: 12/27/2017 37 Ayamok-gil, Sojeong-myeon, Sejong, KOREA, REPUBLIC OF (SOUTH) 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 53 - - - - Cosmetics Date Published: 12/27/2017 Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/27/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/27/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 64 - - - -- Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products **Nowcos Nots** Date Published: 12/27/2017 371-17 Byc Highway, Seoul, KOREA, REPUBLIC OF (SOUTH) 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 12/27/2017 Desc: All Drug and Drug Products

53 - - - - Cosmetics

Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice.

Date Published: 12/27/2017

Desc: All Drug and Drug Products Notes: For Industry Codes 50 and 53; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 12/27/2017 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 12/27/2017 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/27/2017 Notes: All Drug and Drug Products Seindni Co., Ltd. Date Published: 08/23/2017 Seongbuk-gu, 610-304 16, Gireum-ro, Seoul, KOREA, REPUBLIC OF (SOUTH) 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 08/23/2017 Notes: All Drugs and Drug Products; (GMP) Good Manufacturing Practices Date Published: 11/26/2018 Soleo (Ju)Solleocgpmgongjang , 24 Sandan-Ro , Pyeongtaek, Gyeonggi KOREA, REPUBLIC OF (SOUTH) 53 E - - 06 Shampoos (Hair Preparations, Non-coloring) Date Published: 11/26/2018 Desc: All Drug and Drug Products Notes: For 53E[][]06; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/26/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 11/26/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drug and Drug Products 62 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drug and Drug Products 63 - - - -- Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/26/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/26/2018

Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

Date Published: 11/26/2018

## **MALAYSIA**

Date Published: 03/29/2019 Luen Fook Medicine Sdn. Bhd. Taman Periindustrian Sri Plentong, No 6 Jalan Sri Plentong 5, Masai, Johor MALAYSIA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/29/2019 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

#### **MEXICO**

Farma Quimia S.A. de C.V. Av Andre Marie Ampere No 11, Parque Industrial Cuamatla, Cuautitlan Izcalli, Mex MEXICO 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/23/2012

Notes: All Drug Products

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug Products

60 - - - - Human and Animal Drugs

Notes: All Drug Products

61 - - - - Human and Animal Drugs

Notes: All Drug Products

62 - - - - Human and Animal Drugs

Notes: All Drug Products

63 - - - -- Human and Animal Drugs

Notes: All Drug Products

64 - - - - Human and Animal Drugs

Notes: All Drug Products

65 - - - - Human and Animal Drugs

Notes: All Drug Products

66 - - - -- Human and Animal Drugs

Notes: All Drug Products

Jabones Y Productos Especializados SA de CV

Cernicalo 155, Col. La Aurora, Guadalajara, Guadalajara, Jalisco MEXICO

53 J - - -- Personal Cleanliness

Desc: All Drug and Drug Products

Notes: For Industry Code 53; only drug and drug products are subject to DWPE under this notice.

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Date Published: 02/23/2012

Date Published: 08/01/2018

Date Published: 08/01/2018

Date Published: 08/01/2018

Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 08/01/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 08/01/2018 Notes: All Drug and Drug Products PROSANA DISTRIBUCIONES SA DE CV Date Published: 07/12/2017 Calle Oriente 225 97-1, Col. Agricola Oriental, Iztacalco, Ciudad De Mexico, Ciudad de Mexico MEXICO 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 07/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Prosintesis S.A. de C.V. Date Published: 06/17/2015 Avenida Educacion S/N, Jilotzingo, Pueblo Santa Maria Mazatla, Mexico MEXICO 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 06/17/2015 Notes: Problems: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 06/17/2015

Notes: Problems: (GMP) Good Manufacturing Practices

Notes: Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Date Published: 06/17/2015

#### **NETHERLANDS**

BiB Production & Packaging B.V.

Randweg 7 , Roermond, Limburg NETHERLANDS

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug and Drug Products

60 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

61 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

63 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

64 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

65 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products Date Published: 08/08/2018

#### **NEW ZEALAND**

Jaychem Industries Ltd

3 Kordel Place, East Tamaki, Auckland, NEW ZEALAND

55 - - - -- Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug and Drug Products

60 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

61 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

62 - - - - Human and Animal Drugs Notes: All Drug and Drug Products

63 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

64 - - - Human and Animal Drugs

Notes: All Drug and Drug Products

65 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

66 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

Date Published: 12/22/2014

### **SINGAPORE**

Licht Far East (S) Pte Ltd

2 Woodlands Sector 1, #05-04, Singapore, SINGAPORE

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Date Published: 03/28/2014

Date Published: 03/28/2014

Date Published: 03/28/2014

Date Published: 03/28/2014

Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices Opto-Pharm Pte Ltd. Date Published: 05/15/2019 13 Tuas Avenue 12, Singapore, SINGAPORE 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/15/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/15/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 61 - - - -- Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 05/15/2019 Notes: All Drug and Drug Products 83 L - - OP Solution, Antimicrobial Date Published: 05/15/2019 Desc: All Drug and Drug Products Notes: Date Published: 05/15/2019 86 L - - PN Accessories To Contact Lenses - Cleaning And Wetting Agents Desc: All Drug and Drug Products Notes: 86 M - - SI Solution, Cleaning/Lubricating, Articifial Eye Date Published: 05/15/2019 Desc: All Drug and Drug Products

## **SOUTH AFRICA**

Date Published: 09/17/2010 Clover S.A. (Pty)Ltd 200 Constantia Drive, Roodepoort, Gauteng SOUTH AFRICA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/17/2010 Notes: All sterile drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/17/2010 Notes: All sterile drug products 60 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All sterile drug products 61 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All sterile drug products 62 - - - - Human and Animal Drugs Date Published: 09/17/2010 Notes: All sterile drug products 63 - - - -- Human and Animal Drugs Date Published: 09/17/2010

Notes:

Notes: All sterile drug products 64 - - - - - Human and Animal Drugs Notes: All sterile drug products 65 - - - - - Human and Animal Drugs Notes: All sterile drug products 66 - - - - - Human and Animal Drugs

Notes: All sterile drug products

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

**SPAIN** Date Published: 10/12/2017 Casmara Cosmetics, S.A. CALLE CIUTAT DE LLIRIA (POL IND) 29, Paterna, SPAIN 53 - - - - Cosmetics Date Published: 10/18/2017 **Desc: Cosmetics** Notes: Problem(s); (GMP) Good Manufacturing Practices; For Industry Code 53; only drug and drug products are subject to DWPE under this notice 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - -- Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 10/12/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Dysers S.A.L. Date Published: 09/10/2009 Depositos 12, Segovia, SPAIN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 60 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 61 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 62 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 63 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 64 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 65 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 66 - - - - Human and Animal Drugs Date Published: 09/10/2009 Notes: Non-sterile bulk drug products 5/1/1992 Date Published: 10/01/2013 Jabones Pardo S.A.

Calle Sierra Nevada 1, Fuenlabrada, Madrid SPAIN

53 - - - - Cosmetics

Date Published: 10/01/2013

Desc: All drugs and drug products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/01/2013 Notes: All drugs and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 10/01/2013 Desc: All drugs and drug products 60 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products 61 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products 62 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products 64 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products 65 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products 66 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products Date Published: 10/28/2016 Natura Bisse International, Inc. Artesans, Parque Tecnologico Del Valles, Cerdanyola Del Valles, Barcelona SPAIN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 10/28/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Date Published: 11/16/2018 **Proandre SL** Calle Conestable De Portugal 43-45, Granollers, Barcelona SPAIN 53 - - - - Cosmetics Date Published: 11/16/2018 Desc: All Drug and Drug Products Notes: For 53[[[[[]]]; only drug and drug products are subject to DWPE under this notice. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/16/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 11/16/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 11/16/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 11/16/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 11/16/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 11/16/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 11/16/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 11/16/2018 Notes: All Drug and Drug Products

66 - - - -- Human and Animal Drugs

Notes: All Drug and Drug Products

#### **TAIWAN**

Beanne Chemical Co. Date Published: 09/28/2012 No. 28, Lane 456, Fongihou Road, Shengang District, Taichung City, TAIWAN 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 09/28/2012 Desc: All drug and drug products 53 - - - - Cosmetics Date Published: 09/28/2012 Desc: All drug and drug products 56 - - - - Antibiotics (Human/Animal) Date Published: 09/28/2012 Desc: All drug and drug products Date Published: 01/08/2018 Polaroisin International Co., Ltd. Xinzhuang District, NO 173, 10 F; Siyuan Rd., New Taipei City, TAIWAN 53 L - - -- Skin Care Prep Date Published: 01/08/2018 Desc: All Drug and Drug Products Notes: For industry code 53L; only products found to be drug products are subject to DWPE under this listing 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/08/2018 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 01/08/2018 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 01/08/2018 Notes: All Drug and Drug Products Taiwan Three Mast Pharmaceutical Co., Ltd. Date Published: 09/04/2012 3 Jingzhong Rd., Tainan City, TAIWAN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/04/2012 60 - - - - Human and Animal Drugs Date Published: 09/04/2012 61 - - - - Human and Animal Drugs Date Published: 09/04/2012 62 - - - - Human and Animal Drugs Date Published: 09/04/2012 63 - - - - Human and Animal Drugs Date Published: 09/04/2012 64 - - - - Human and Animal Drugs Date Published: 09/04/2012 65 - - - - Human and Animal Drugs Date Published: 09/04/2012 66 - - - - Human and Animal Drugs Date Published: 09/04/2012 Vida International, Inc. Date Published: 03/11/2019 No. 263-2 Zhongshan N. Rd., Dayuan Dist., Taoyuan City, TAIWAN 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/11/2019 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/11/2019 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/11/2019 Notes: All Drug and Drug Products

Date Published: 11/16/2018

62 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 63 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 64 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 65 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products 66 - - - - - Human and Animal Drugs Notes: All Drug and Drug Products Notes: All Drug and Drug Products

Date Published: 03/11/2019

#### **THAILAND**

PAN RAJDHEVEE GROUP PUBLIC COMPANY LIMITED Date Published: 03/10/2015 50/234-275 MOO 3, LAT SA WAI, LAM LUK KA, Lam Luk Ka, Pathum Thani THAILAND 53 - - - - Cosmetics Date Published: 03/10/2015 Notes: All Drug and Drug Products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/10/2015 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/10/2015 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 66 - - - -- Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products PCIC Co., Ltd. Date Published: 03/10/2015 Lam Luk Ka, 73 Moo 12, Pracharaduthid Rd., Bang Phli, Samut Prakan THAILAND 53 - - - - Cosmetics Date Published: 03/10/2015 Notes: All Drug and Drug Products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/10/2015 Notes: All Drug and Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 03/10/2015 Notes: All Drug and Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/10/2015 Notes: All Drug and Drug Products

#### **TRINIDAD & TOBAGO**

International Cosmetics Limited Date Published : 11/28/2017

Date Published: 02/03/2015

Date Published: 09/10/2009

Date Published: 07/01/2019

91/94

ICL Drive Bhagowtie Trace, San Juan, TRINIDAD & TOBAGO

53 I - - 02 Mouthwashes and Breath Fresheners (Liquids and Sprays), without Fluoride (Oral Hygiene Products)

Desc: Mouthwashes and Breath Fresheners

Notes: For Product Code 53I[[]02; only drug and drug products are subject to DWPE under this notice

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs 65 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

# TUNISIA

Unite de Fabrication de Medicaments SA Date Published : 02/03/2015

Zone Industrielle , Kalaa El Kebira , Sousse, Sousse TUNISIA

65 F - - 06 Water, Purified (Eyewash)
Desc: Cederroth Emergency Eye Wash

# TURKEY

Ansa Date Published : 09/10/2009

UNKNOWN, Izmit, TURKEY

56 - - - - Antibiotics (Human/Animal)

DEVA HOLDING A.S.

1 Kucukcekmece, Istanbul, TURKEY

Halkalimerkez Mah., Halkali Cad. Merkez Mahalles, Kucukcekmece, Istanbul TURKEY

61 K - - 68 Temozolomide (Anti-Cholinergic)

Desc: Temozolomide

DEVA HOLDING AS Date Published: 07/01/2019

61 K - - 68 Temozolomide (Anti-Cholinergic)

Desc: Temozolomide

Deva Holding AS - Cerkezkoy Subesi

Organize Fatih Bulvar Fatih Bulvar 32 Cerkezkoy, Cerkezkoy, Tekirdag TURKEY

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug and Drug Products

60 - - - - Human and Animal Drugs

Notes: All Drug and Drug Products

https://www.accessdata.fda.gov/cms\_ia/importalert\_189.html

61 - - - - Human and Animal Drugs Date Published: 07/01/2019 Notes: All Drug and Drug Products 62 - - - - Human and Animal Drugs Date Published: 07/01/2019 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 07/01/2019 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 07/01/2019 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 07/01/2019 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 07/01/2019 Notes: All Drug and Drug Products Deva Holding As - Kartepe Uretim Tesisleri Date Published: 07/01/2019 Ankara Caddesi 2 Dumlupinar Mahallesi, Kartepe, Kocaeli TURKEY 61 K - - 68 Temozolomide (Anti-Cholinergic) Date Published: 07/01/2019 Desc: Temozolomide Mustafa Nevzat Ilac Sanayii, A.S. Date Published: 04/16/2013 Cobancesme Mah., Sanayi Cad., Bahcelievler, Istanbul TURKEY 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 04/16/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 04/16/2013 Notes: All drug and drug products GPI=DR; 56[][][

# **UNITED ARAB EMIRATES**

Julphar Gulf Pharmaceutical Industries Digdaga, Airport Road, Ra's al Khaymah, UNITED ARAB EMIRATES 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/31/2012 Notes: All Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 01/31/2012 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products 61 - - - -- Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products 63 - - - -- Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products 66 - - - - Human and Animal Drugs Date Published: 01/31/2012 Notes: All Drug Products

## **UNITED KINGDOM**

Hampshire Chemicals, Ltd. Date Published: 09/10/2009

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs 62 - - - - Human and Animal Drugs

63 - - - - Human and Animal Drugs

64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

Date Published: 04/16/2013 Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 04/16/2013

Date Published: 01/31/2012

Seal Sands Road, Middlesborough, Cleveland UNITED KINGDOM 56 - - S -- Antibiotics (Human/Animal), Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996 60 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996 61 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996 62 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996

63 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf

Notes: All bulk pharmaceuticals 1/26/1996 64 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996

65 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996

66 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes: All bulk pharmaceuticals 1/26/1996

#### **VENEZUELA**

LABORATORIOS LO OFTALMI CA Date Published: 05/14/2010 CTO. EMPRESARIAL "RS", CALLE 6, ZONA INDUSTRIAL LA URBINA, Caracas, VE-NOTA VENEZUELA 56 - - - - Antibiotics (Human/Animal) Date Published: 05/14/2010 Notes: All Drug Products 73 - - - - Anesthesiology Date Published: 05/14/2010 Notes: All Drug Products 74 - - - - Cardiovascular Date Published: 05/14/2010 Notes: All Drug Products 76 - - - - Dental Date Published: 05/14/2010 Notes: All Drug Products 77 - - - - Ear, Nose And Throat Date Published: 05/14/2010 Notes: All Drug Products 78 - - - - Gastroenterological & Urological Date Published: 05/14/2010 Notes: All Drug Products 79 - - - - General & Plastic Surgery Date Published: 05/14/2010 Notes: All Drug Products 80 - - - - General Hospital/Personal Use Date Published: 05/14/2010 Notes: All Drug Products 84 - - - - Neurological Date Published: 05/14/2010 Notes: All Drug Products 85 - - - - Obstetrical & Gynecological Date Published: 05/14/2010 Notes: All Drug Products 86 - - - - Ophthalmic Date Published: 05/14/2010 Notes: All Drug Products 87 - - - - Orthopedic Date Published: 05/14/2010 Notes: All Drug Products 89 - - - - Physical Medicine Date Published: 05/14/2010 Notes: All Drug Products 90 - - - - Radiological Date Published: 05/14/2010 Notes: All Drug Products

Laboratorios L.O. Oftalmi, C.A. Ca. Leo 6, Zona Industrial de La Urbina, Caracas, D.F. VENEZUELA

55 - - - - Pharm Necess & Ctnr For Drug/Bio

Notes: All Drug Products

56 - - - - Antibiotics (Human/Animal)

Notes: All Drug Products

60 - - - - Human and Animal Drugs

Notes: All Drug Products

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs

Notes: All Drug Products

62 - - - - Human and Animal Drugs

Notes: All Drug Products

63 - - - - Human and Animal Drugs

Notes: All Drug Products

64 - - - - Human and Animal Drugs

Notes: All Drug Products

65 - - - - Human and Animal Drugs

Notes: All Drug Products

66 - - - - Human and Animal Drugs

Notes: All Drug Products

Date Published: 05/14/2010

Date Published: 05/14/2010