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)

4

■ 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: 09/28/2018

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. ***

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-s 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 and controls used in its manufacture and control of pharmaceutical 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

Delta Laboratories Pty Ltd	Date Published : 09/28/2017
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	D / D II 1 00/00/00/7
65 Human and Animal Drugs	Date Published: 09/28/2017
Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices	D
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	D + D + F + D + 00/00/0040
63 Human and Animal Drugs	Date Published: 03/08/2018
Notes: All Drug and Drug Products	Data Dublishad, 02/00/2010
64 Human and Animal Drugs	Date Published: 03/08/2018
64 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	Date Published: 03/08/2018 Date Published: 03/08/2018
64 Human and Animal Drugs Notes: All Drug and Drug Products 65 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 03/08/2018
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	
64 Human and Animal Drugs Notes: All Drug and Drug Products 65 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 03/08/2018

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

57 Oatley Court , Belconnen, AUSTRALIA

Notes: Nexavir

Date Published: 09/10/2009

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 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

Date Published: 01/18/2011 Laboratoria Qualiphar NV Rijksweg 9, Bornem, Antwerp BELGIUM 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/18/2011 Notes: All drug products 60 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 61 - - - -- Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 62 - - - -- Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 63 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 64 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 65 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products 66 - - - - Human and Animal Drugs Date Published: 01/18/2011 Notes: All drug products

BRAZIL

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

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 10/20/2017

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Lima & Pergher Ind. Com. Rep Ltda

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

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

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

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

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

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

62 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Date Published: 07/15/2016 Lima & Pergher Industria e Comercio S/A Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 07/15/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

CANADA

Aleeda Inc 7115 Tomken Rd , Mississauga, ON CANADA	Date Published : 05/29/2012
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/29/2012
60 Human and Animal Drugs	Date Published: 05/29/2012
61 Human and Animal Drugs	Date Published: 05/29/2012
62 Human and Animal Drugs	Date Published: 05/29/2012
63 Human and Animal Drugs	Date Published: 05/29/2012
64 Human and Animal Drugs	Date Published: 05/29/2012
65 Human and Animal Drugs	Date Published: 05/29/2012
66 Human and Animal Drugs	Date Published: 05/29/2012
Attix Pharmaceuticals Inc.	Date Published : 02/18/2015
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	Date Published: 02/18/2015

66 - - - - Human and Animal Drugs

56 - - - - Antibiotics (Human/Animal)

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

63 - - - - Human and Animal Drugs

Date Published: 07/15/2016

Date Published: 02/18/2015

64 - - - - Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 02/18/2015 Notes: All drugs and drug products; Problems: (GMP) Good Manufacturing Practices Date Published: 10/19/2017 Aztex Enterprises Ltd. 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 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 Aztex Enterprises Ltd. 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 **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 Date Published: 07/24/2018 Bill Beauty and Health Products Ltd. 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. 54 B - - -- Mineral 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. 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/24/2018 Notes: All Drug and Drug Products 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 63 - - - - Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products

65 - - - - Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 06/02/2017 Notes: All Drug and Drug Products Centre for Probe Development & Commercialization Date Published: 08/01/2018 Nrb A316, 1-1280 Main St W, Hamilton, Ontario CANADA 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 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

Date Published: 12/10/2015 63 - - - - Human and Animal Drugs 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 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

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

66 - - - - Human and Animal Drugs

Date Published: 05/03/2017

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/Uncony 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 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. 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 61 - - - - Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products 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

64 - - - -- Human and Animal Drugs Date Published: 02/23/2012

Notes: All Drug Products

65 - - - -- Human and Animal Drugs Date Published: 02/23/2012

Notes: All Drug Products

66 - - - -- Human and Animal Drugs Date Published: 02/23/2012

Notes: All Drug Products

Ross Healthcare Inc.

6-1520 Cliveden Ave , Delta, British Columbia CANADA 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: 11/30/2017

CHINA

Attix Pharmaceuticals (Xiamen)

Xiangyue Road, NO. 7 Xinganlu, Shamen, Fujian CHINA

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)

Notes: 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

Ausmetics Daily Chemicals (Guangzhou) Co., Ltd.

Economic And Technical , NO. 1 Jinxiulu; Huangpu , Guangzhou, Guangdong CHINA

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

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

Date Published: 05/13/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016 56 - - - - Antibiotics (Human/Animal) 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.

No 7 Fuqiandongjie, Shunyi District, Shunyiqu, Beijingshi CHINA

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

Notes: All drug products; Firm refused FDA inspection

56 - - - - Antibiotics (Human/Animal)

Notes: All drug products; Firm refused FDA inspection

60 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

61 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

62 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

63 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

64 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

65 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

66 - - - - Human and Animal Drugs

Notes: All drug products; Firm refused FDA inspection

Beijing Taiyang Pharmaceutical Industry Co Ltd

No 1 Shuangqiao Xili, Chaoyang, Beijing, Beijing 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

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

01 - - - - - Human and Amma Drugs

Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - -- Human and Animal Drugs

02 - - - - Hullian and Amiliai 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: 07/22/2014

Date Published: 04/29/2016

Date Published: 06/29/2017

Bluetech Chemicals Limited Date Published: 09/17/2010 Rm 703, No. 25, Lane 175, Shanghai, CN-31 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 Date Published: 09/17/2010 Boai Xinda Food Co., Ltd. The North Of Dong Wang He, Xiaojing, Boai, Henansheng 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 **CR Zizhu Pharmaceutical Co Ltd** Date Published: 03/08/2017 No. 27, Chaoyang North Rd, Chaoyang District, Beijing, Haidian 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

Changshu Huagang Pharmaceuticals Co., Ltd Date Published: 09/30/2013 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 Date Published: 08/11/2017 **Changzhou Anyuan Import & Export** 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 66 - - - - Human and Animal Drugs Date Published: 08/11/2017 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

Notes: All Drug and Drug Products

Date Published: 05/04/2017

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 74 L - - IS Heparin Coating Chemicals, 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 88 *I - - AZ* 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 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 Date Published: 09/10/2009 63 - - - - Human and Animal Drugs 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 Chongqing 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 Chongqing Paiquiang 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

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

61 - - - - Human and Animal Drugs

Date Published: 11/22/2016

62 - - - - Human and Animal Drugs

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 Date Published: 05/10/2012 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. Date Published: 05/23/2017 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.

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

Date Published: 11/22/2016

66 - - - - Human and Animal Drugs

Date Published: 05/23/2017

Date Published: 05/23/2017

Date Published: 05/23/2017

Date Published: 05/23/2017

Date Published: 02/14/2018

Date Published: 02/14/2018

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.

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 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

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

Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs

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

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

62 - - - -- Human and Animal Drugs

Date Published: 02/14/2018

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
Date Published: 02/14/2018

Notes: All Drug and Drug Products

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

Notes: All Drug and Drug Products

FriendsUnion(Tianiin) enterprises ltd.

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

Date Published: 09/17/2010 64 - - - - Human and Animal Drugs 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 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, Baiyun, Guangzhou, 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, Bldg.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
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

Hangzhou Facecare Cosmetics Co., Ltd.

Dev. Area, Hangzhou Economic; 755 Nongken Road, Hangzhou, 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

Hangzhou Karic Commodities Co., Ltd.

West Lake Science And , No 2 Fifth Avenue , Hangzhou, Zhejiang CHINA

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

Hangzhou Zhongbo Industrial Co., Ltd.

Yuhang District , Changle Industrial Zone , Hangzhou, Zhejiang CHINA

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

Notes: All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 03/14/2016

Date Published: 09/14/2017

Date Published: 07/16/2018

Date Published: 09/28/2018

Date Published: 09/28/2018

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 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/08/2016 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 Date Published: 11/01/2017 56 - - - - Antibiotics (Human/Animal) 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 Fl. 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: 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: 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.

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

95 - - - - Light Emitting Non-Device Products

Desc: All Drug and Drug Products

notice.

Date Published: 06/07/2017

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 Notes: All Drug and Drug Products Jilin Shulan Synthetic Pharmaceutical Co. Ltd. Date Published: 03/01/2018 No. 2066 Peoples Main Road, Shulan, Jilin, Jilin CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio 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 Date Published: 09/10/2009 56 - - - - Antibiotics (Human/Animal) 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 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 **Longbow First Aid Products Manufactory** Date Published: 08/17/2018 Building F/2, A3 Guiping Road; Hantian Industrial Park, Foshan, Guangdong CHINA 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 Date Published: 08/17/2018 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 08/17/2018 Notes: All Drug and Drug Products 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. Date Published: 02/15/2017 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) Notes: All Drug and Drug Products; For Industry Code 54, only drug and drug products are subject to DWPE under this notice 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 Date Published: 02/15/2017 Notes: All Drug and Drug Products 61 - - - - Human and Animal Drugs Date Published: 02/15/2017 Notes: All Drug and Drug Products 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 Date Published: 02/15/2017 Notes: All Drug and Drug Products Date Published: 12/21/2017 Ming Fai Industrial (Shenzhen) Co LTD 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 Nanjing Maohai Biotech Co. Date Published: 10/18/2011 8 Developing Zone, Yaxi Town, Gaochun County, Nanjing Jiangsu Province, CHINA 55 R - - 75 Crude Heparin (Pharmaceutic Necessity) Date Published: 10/18/2011 Desc: Crude Heparin (Pharmaceutical Necessity) 61 L - - 08 Heparin Sodium (Anti-Coagulant) Date Published: 10/18/2011 Desc: Heparin Sodium (Anti-Coagulant) Nanjing Pharmaceutical Factory Co., Ltd. Date Published: 09/13/2018 9 Fang Shuilu, Liuhe, Nanjing, Jiangsu CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 09/13/2018 Notes: All Drug; All Antibiotics; (GMP) Good Manufacturing Practices Nantong Strip Medical Supply Co Ltd Date Published: 03/27/2013 Building A, 182 Yuelong South Rd, Nantong, Jiangsu CHINA 50 - - - - Color Additiv Food/Drug/Cosmetic Date Published: 03/27/2013 Notes: All Drug Products 53 - - - - Cosmetics Date Published: 03/27/2013 Notes: All Drug Products 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 03/27/2013 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 61 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 63 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 66 - - - - Human and Animal Drugs Date Published: 03/27/2013 Notes: All Drug Products 80 - - - - General Hospital/Personal Use Date Published: 03/27/2013 Notes: All 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

Date Published: 03/05/2013 56 - - - - Antibiotics (Human/Animal) 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.

137 Bali Road , Zhangqi Town , Zhejang, 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

Northeast Pharmaceutical Group Co., Ltd.

37 Zhonggongbeijie, Tiexi, Chenyang, Liaoning CHINA

45 - - - - 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

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

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

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

Date Published: 11/22/2016

Date Published: 09/10/2009

Date Published: 08/28/2010

Date Published: 08/28/2010

Date Published: 08/28/2010

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPF

61 - - - - Human and Animal Drugs

Date Published: 09/10/2009 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

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

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

61 - - - - Human and Animal Drugs

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

62 - - - - Human and Animal Drugs

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

63 - - - - Human and Animal Drugs

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

64 - - - - Human and Animal Drugs

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

65 - - - - Human and Animal Drugs

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

66 - - - - Human and Animal Drugs

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

Date Published: 09/10/2009

Date Published: 12/27/2017

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 Date Published: 08/22/2017 Shandong Vianor Biotech Co., Ltd. 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 74 L - - IS Heparin Coating Chemicals, 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 88 *I - - AZ* Heparin Date Published: 09/10/2009 Notes: All heparin products 1/21/2009 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 Date Published: 04/03/2013 62 - - - - Human and Animal Drugs 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 Notes: (GMP) Good Manufacturing Practices 53 F - - 04 Hair Shampoos (Coloring) (Hair Coloring Preparations) Date Published: 03/28/2014 Desc: Dandruff Shampoo 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 60 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; (GMP) Good Manufacturing Practices 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 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 66 - - - - Human and Animal Drugs Date Published: 03/28/2014 Notes: All Drugs; (GMP) Good Manufacturing Practices 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 74 L - - IS Heparin Coating Chemicals. 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 88 *I - - AZ* Heparin Date Published: 09/10/2009 Notes: All Heparin Products 1/21/2009 Date Published: 09/10/2009 Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd. 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 only. 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 only 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 Date Published: 09/14/2017 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 56 - - - - Antibiotics (Human/Animal) Date Published: 09/14/2017 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices

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

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

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

60 - - - - Human and Animal Drugs

61 - - - - Human and Animal Drugs

62 - - - - Human and Animal Drugs

Date Published: 09/14/2017

Date Published: 09/14/2017

Date Published: 09/14/2017

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 89 - - - - Physical Medicine Date Published: 08/23/2018 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 Date Published: 07/10/2014 Suzhou No. 4 Pharmaceutical Factory 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 The West of Qiliqiao , Economic Development Zone , Taizhou, Jiangsu Province CHINA 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 01/15/2013 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 01/15/2013 56 - - - - Antibiotics (Human/Animal) Date Published: 01/15/2013 60 - - - - Human and Animal Drugs Date Published: 01/15/2013 61 - - - - Human and Animal Drugs Date Published: 01/15/2013 62 - - - - Human and Animal Drugs Date Published: 01/15/2013

63 - - - - Human and Animal Drugs Date Published: 01/15/2013 64 - - - - Human and Animal Drugs Date Published: 01/15/2013 65 - - - - Human and Animal Drugs Date Published: 01/15/2013 66 - - - - Human and Animal Drugs Date Published: 01/15/2013 80 L - - KB Pad. Alcohol 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 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 Tianjin Boai Pharmaceutical Ltd. co. Date Published: 09/17/2010 6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , 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 Date Published: 09/17/2010 66 - - - - Human and Animal Drugs Notes: All drug products Tianjin Zhongan Pharmaceutical Co., Ltd. Date Published: 02/11/2016 Xiqing, 188 Fukang Road, Tianjin, Tianjin CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 56 - - - - Antibiotics (Human/Animal) Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 02/11/2016 Notes: Problem: (GMP) Good Manufacturing Practices 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

Date Published: 02/11/2016 64 - - - - Human and Animal Drugs 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 Wuhan Pharmaceutical Industry Park, East Lake High-Tech, 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 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) Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 05/13/2016 Notes: All Drugs and Drug Products; Problem(s): (GMP) Good Manufacturing Practices Xinxiang Pharmaceutical Co. Ltd. Date Published: 04/06/2016 NO. 30 Jianshe West Road, Beigandao, 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

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.

Xinxiang Tuoxin Biochemical Co. Ltd

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

53 - - - - Cosmetics

Date Published: 04/06/2016

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.

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

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 I - - 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

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: 08/12/2016

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

61 - - - - 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.

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

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

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)

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

Yicheng Goto Pharmaceuticals Co., Ltd

Group 1 Gaokeng, Yicheng, Xiangyang, Hubei CHINA

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

Date Published: 08/11/2017

Date Published: 01/10/2018

Date Published: 01/10/2018

Date Published: 01/10/2018

Date Published: 01/10/2018

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)

Coastal Industrial Zone, Chuannan No. 1 Branch No. 9, Donghai 5th Avenue, Linhai, Taizhou Zhejiang CHINA

Zhejiang Huahai Pharmaceutical

Date Published: 09/28/2018

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, No. 5 Industry Road, 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 Date Published: 12/28/2017 Notes: All Drug and Drug Products 63 - - - - Human and Animal Drugs Date Published: 12/28/2017 Notes: All Drug and Drug Products 64 - - - - Human and Animal Drugs Date Published: 12/28/2017 Notes: All Drug and Drug Products 65 - - - - Human and Animal Drugs Date Published: 12/28/2017 Notes: All Drug and Drug Products 66 - - - - Human and Animal Drugs Date Published: 12/28/2017 Notes: All Drug and Drug Products Zhejiang Qianfei Enterprise Co. Ltd. Date Published: 11/24/2015 No 173 Wulian Road, Yiwu, Jinhua, Zhejiang CHINA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 11/24/2015 Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices 60 - - - - Human and Animal Drugs Date Published: 11/24/2015 Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 11/24/2015 Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 11/24/2015 Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs Date Published: 11/24/2015 Notes: All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 11/24/2015

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

Date Published: 11/24/2015

Date Published: 11/24/2015

Date Published: 03/01/2011

Date Published: 02/08/2018

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 Date Published : 03/01/2011

A 8, Copenhagen, DENMARK

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

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

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

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

Leo Pharmaceutical Products Date Published : 03/01/2011

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.

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

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: 02/08/2018

Date Published: 02/08/2018

FRANCE

Date Published: 01/17/2018 **BR SAS**

28 Rue De La Procession, Suresnes, FRANCE

53 - - - - Cosmetics Date Published: 01/17/2018

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: 01/17/2018

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.

63 - - - - 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.

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 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

Notes: Selenomethionine 75 injection

63 - - - - Human and Animal Drugs 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

Date Published: 09/10/2009

66 - - - - Human and Animal Drugs

Notes: Selenomethionine 75 injection

Notes: Selenomethionine 75 injection

Compagnie Oris Industrie Lpib Date Published: 09/10/2009

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

Date Published: 09/10/2009

Date Published: 09/10/2009

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 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 07/08/2013 56 - - - - Antibiotics (Human/Animal) 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

GREECE

CHIA GH LTD.Date Published : 05/06/2013Ag. Mina 144 , Chios, GREECE55 - - - - - Pharm Necess & Ctnr For Drug/BioDate Published: 05/06/201356 - - - - - Antibiotics (Human/Animal)Date Published: 05/06/201360 - - - - Human and Animal DrugsDate Published: 05/06/201361 - - - - Human and Animal DrugsDate Published: 05/06/2013

Date Published: 05/06/2013 62 - - - - Human and Animal Drugs 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

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 Date Published: 08/31/2013 Desc: All drugs and drug products 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 08/31/2013 Desc: 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 Desc: 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 62 - - - - Human and Animal Drugs Date Published: 08/31/2013 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 Desc: All drugs and drug products 88 - - - - Pathology Date Published: 08/31/2013 Desc: All drugs and drug products

Chan Yat Hing Medicine Factory

Flat 3, 9/F, Fuk Keung Industrial Bldg., Mong Kok, Kowloon HONG KONG

53 - - - - Cosmetics

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

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

Date Published: 12/03/2015

Date Published: 01/07/2016

Date Published: 12/03/2015

Date Published: 12/03/2015

Date Published: 12/03/2015

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 Date Published: 12/03/2015 66 - - - - Human and Animal Drugs 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 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 Date Published: 03/04/2014 **Peking Medicine Manufactory** 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 62 - - - -- Human and Animal Drugs Date Published: 08/31/2013 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 66 - - - - 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; These products are excluded from dwpe: Amikacin/56D[[[]06; Bleomycin / 56H[][]10 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 **INDIA** Aadivighnesh Chem PVT. LTD. Date Published: 05/05/2014 A/7 Badrinath Apartment, Simpoli Road; Borivali West, Mumbai, 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 64 - - - - Human and Animal Drugs Date Published: 08/21/2015 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 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 Drugs; 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 Drugs; Problem(s): (GMP) Good Manufacturing Practices 61 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drugs; These products are excluded from DWPE: Riluzole tablets (62J[[[]16) and Abacavir tablets (62V[[[]17) due to potential drug shortage concerns. 63 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs Date Published: 04/12/2018 Notes: All Drugs; Problem(s): (GMP) Good Manufacturing Practices **Badrivishal Chemicals & Pharmaceuticals** Date Published: 12/19/2016 Gat No. 29. Village Jambwade (Induri) . Post Sudumbre. Taluka Mayal . 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;

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: Ondansetron inj. Antiemetic (for nausea/vomiting)/61T[][]26 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 Efavirenz / 62V[][]24 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 Fleming Laboratories Ltd. Date Published: 10/20/2017 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 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

Goran Pharma Pvt Ltd

Gdic-I, Bhavnagar Road, Sihor, Gujarat INDIA

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

Health Biotech Limited

District Solan, Nalgarh Road, Baddi, Himachal Pradesh INDIA

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

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

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 10/20/2017

Date Published: 03/05/2018

Date Published: 04/03/2018

Date Published: 04/03/2018

Date Published: 04/03/2018

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; The following drugs are excluded from DWPE: Piperacillin / Tazobactam - 56B[][]56; Cefazolin - 56C[][]11; Cefoxitin - 56C[][]62; Cefepime - 56C[][]53; Ceftriaxone - 56C[][]70 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; The following drugs are excluded from DWPE: Cefoxitin - 61F[[[]19; Meropenem - 61G[[[]80 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; The following drugs are excluded from DWPE: Imipenem and Cilastatin - 64U[[]04 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 Date Published: 03/24/2015 **Ipca Laboratories LTd** 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: 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 **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[] 1106 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 JT Cosmetics & Chemicals Pvt Ltd. Date Published: 06/11/2018 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 Kamud Drugs Pvt. Ltd. Date Published: 07/10/2013

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 Date Published: 08/21/2017 Kim Chemicals Private Ltd. 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 Date Published: 07/10/2013 Konduskar Laboratories Pvt Ltd 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 **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 56 - - - - Antibiotics (Human/Animal) Date Published: 08/25/2017 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

Notes: All Drug and Drug Products

Date Published: 12/13/2017

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 Date Published: 03/12/2014 Marck Biosciences Ltd. 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, Mid 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 Date Published: 12/08/2015 Pan Drugs Limited 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 Date Published: 12/08/2015 66 - - - - Human and Animal Drugs 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 Date Published: 09/11/2015 Polydrug Laboratories Pvt. Ltd. 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 66 - - - - Human and Animal Drugs Date Published: 06/10/2013 **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

Date Published: 06/11/2013 61 - - - - Human and Animal Drugs 62 - - - - Human and Animal Drugs Date Published: 06/11/2013 Date Published: 06/11/2013 63 - - - - Human and Animal Drugs 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 Reine Lifescience Date Published: 03/30/2018 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) Sal Pharma Date Published: 02/15/2017 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 Date Published: 06/20/2013 Sentiss Pharma Pvt. Ltd. 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 65 - - - - Human and Animal Drugs Date Published: 06/20/2013 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 Date Published: 08/13/2015 Sri Krishna Pharmaceuticals Ltd. - Unit II 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 Date Published: 01/13/2011 Stericon Pharma Pvt. Ltd. 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)

3 Industrial Area, Dewas, Madhya Pradesh INDIA

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

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

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)

Tehsil, Simour District, Paonta Sahib, 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 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

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 Limited - Karkhadi	Date Published : 03/12/2014
Plot No. 817/A, Village - Karkhadi , Taluka - Padra District , Vadodara, Gujarat, INDIA	
60 Human and Animal Drugs Desc: All Human Drug Products	Date Published: 03/12/2014
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	Date Fublished: 03/12/2014
63 Human and Animal Drugs	Date Published: 03/12/2014
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Desc: All Human Drug Products	Date Fublished. 03/12/2014
65 Human and Animal Drugs	Date Published: 03/12/2014
Desc: All Human Drug Products	Deta Dublished, 02/42/2044
66 Human and Animal Drugs Desc: All Human Drug Products	Date Published: 03/12/2014
Desc. All Human Drug Froducts	
Unique Chemicals Shiry Mahana Canacli. Thoma Balanur Bood, Navi Mumbai, Maharaahtra INDIA	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	Bate Fabilities. 00/20/2010
55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 06/28/2013
Notes: All drugs and drug products	D-4- Dublish - 4, 00/00/0040
56 Antibiotics (Human/Animal) Desc: All drugs and drug products	Date Published: 06/28/2013
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
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64 Human and Animal Drugs Notes: All drugs and drug products	Date Published: 06/28/2013
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	Date Published: 00/20/2013
54 Vit/Min/Prot/Unconv Diet(Human/Animal)	Date Published: 06/28/2013
Desc: All drugs and drug products	D / D / II / D / 00/00/0040
55 Pharm Necess & Ctnr For Drug/Bio Notes: All drugs and drug products	Date Published: 06/28/2013
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
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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 Vipor Chemicals Private Ltd. Date Published: 07/11/2018 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, Andhra Pradesh 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 **Wockhardt Limited** Date Published: 05/22/2013

H - 14/2 Plot , Biotech Park , Karodi, Maharashtra INDIA

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

Notes: All Drugs and drug products;

Date Published: 05/22/2013

56 Antibiotics (Human/Animal) Notes: All Drugs and drug products;	
	Date Published: 05/22/2013
60 Human and Animal Drugs	Date Published: 05/22/2013
Notes: All Drugs and drug products;	
61 Human and Animal Drugs Notes: All Drugs and drug products;	Date Published: 05/22/2013
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 Notes: All Drugs and drug products;	Date Published: 05/22/2013
64 Human and Animal Drugs	Date Published: 05/22/2013
Notes: All Drugs and drug products	D D
65 Human and Animal Drugs Notes: All Drugs and drug products	Date Published: 05/22/2013
66 Human and Animal Drugs	Date Published: 05/22/2013
Notes: All Drugs and drug products;	
Wockhardt Limited	Date Published : 11/26/2013
L-1, MIDC Area, Jalgaon Road 43, Chikalthana, Aurangabad, Maharashtra INDIA	Data Dublish ad 00/00/2010
50 Color Additiv Food/Drug/Cosmetic Desc: All Drug and Drug Products	Date Published: 09/28/2016
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	Date Fublished. 09/20/2010
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	Bate Fabilities. 11/26/2010
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 (An (62OCA28, 62OCS28)	tinypertensive - part II)
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	Date Published: 11/26/2013
Notes: All Drug and Drug Products 65 Human and Animal Drugs	Date Published: 11/26/2013 Date Published: 11/26/2013
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Notes: All Drug and Drug Products 65 Human and Animal Drugs Notes: All Drug and Drug Products 66 Human and Animal Drugs	Date Published: 11/26/2013
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 Wockhardt, Ltd. Plot 138 GIDC Industrial, Bulk Drug Division, Dist. Bharuch, Ankleshwar, INDIA	Date Published: 11/26/2013 Date Published: 11/26/2013 Date Published: 08/05/2016
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 Wockhardt, Ltd. Plot 138 GIDC Industrial, Bulk Drug Division, Dist. Bharuch, Ankleshwar, INDIA 55 Pharm Necess & Ctnr For Drug/Bio	Date Published: 11/26/2013 Date Published: 11/26/2013
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 Wockhardt, Ltd. Plot 138 GIDC Industrial , Bulk Drug Division, Dist. Bharuch , Ankleshwar, INDIA 55 Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products 56 Antibiotics (Human/Animal)	Date Published: 11/26/2013 Date Published: 11/26/2013 Date Published: 08/05/2016
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Yag Mag Labs Private Limited

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

60 L - - 69 Tramadol HCI (Analgesic)

Desc: Tramadol HCI (Analgesic) 60 L - - 99 Analgesic, N.E.C.

Desc: Tramadol HCI (Analgesic) 64 H - - 02 Guaifenesin (Expectorant)

Desc: Guaifensein (Expectorant)

Date Published: 09/13/2011

Date Published: 09/13/2011

Date Published: 09/13/2011

Date Published: 09/13/2011

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

Date Published: 02/22/2018

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

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

Topchem SRL

Date Published: 11/27/2017

Date Published: 09/10/2009

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 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: 09/10/2009

JAMAICA

P.A. Benjamin Manufacturing Company Limited Date Published: 08/29/2012 95-97 East Street, Kingston, JM-01 JAMAICA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 08/29/2012 60 - - - - Human and Animal Drugs Date Published: 08/29/2012 61 - - - - Human and Animal Drugs Date Published: 08/29/2012 62 - - - - Human and Animal Drugs Date Published: 08/29/2012 63 - - - - Human and Animal Drugs Date Published: 08/29/2012 64 - - - - Human and Animal Drugs Date Published: 08/29/2012 65 - - - - Human and Animal Drugs Date Published: 08/29/2012 66 - - - - Human and Animal Drugs 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

62 - - - - Human and Animal Drugs

Notes: All Drugs Products

63 - - - - Human and Animal Drugs

Notes: All Drugs Products

64 - - - - Human and Animal Drugs

Notes: All Drugs Products

65 - - - - Human and Animal Drugs

Notes: All Drugs Products

66 - - - - Human and Animal Drugs

Notes: All Drugs Products

Daito Kasei Kogyo Co Ltd

441, Kidani, Bizen, Okayama JAPAN

Date Published: 02/13/2013

Date Published: 10/25/2017

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 notice 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 Date Published: 05/06/2013 Kanebo Cosmetics Inc. Odawara-shi Kanagawa 28, Kotobuki-Cho, Odawara, Kanagawa JAPAN 55 - - - - Pharm Necess & Ctnr For Drug/Bio

65 - - - - Human and Animal Drugs

KOREA, REPUBLIC OF (SOUTH)

Amaros Co., Ltd Date Published: 08/23/2017 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) 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

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

66 - - - - Human and Animal Drugs

Date Published: 05/06/2013

Notes: All Drug and Drug Products

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. Date Published: 03/08/2018 Hanbul Cosmetics Co., Ltd 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 K J I Industrial Co., Ltd. Date Published: 09/04/2013 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 , Igsan-Si, Jeonrabug-do 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 62 Human and Animal Drugs	Date Published: 05/06/2013 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
Nowcos Co Ltd	Date Published : 12/27/2017
53714 Segyo Dong , Pyeongtaek, KOREA, REPUBLIC OF (SOUTH)	Data Dublishad, 42/27/2047
50 Color Additiv Food/Drug/Cosmetic Desc: All Drug and Drug Products	Date Published: 12/27/2017
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.	D / D
55 Pharm Necess & Ctnr For Drug/Bio Notes: All Drug and Drug Products	Date Published: 12/27/2017
56 Antibiotics (Human/Animal)	Date Published: 12/27/2017
Notes: All Drug and Drug Products	Bato Fabilioned. 12/21/2011
60 Human and Animal Drugs	Date Published: 12/27/2017
Notes: All Drug and Drug Products	D 1 D 1 1 1 1 10/07/0047
61 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 12/27/2017
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	D-4- Dublish - 4- 40/07/0047
64 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 12/27/2017
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	Date Fublished. 12/21/2017
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	Date i ubilstied. 12/2//2017
56 Antibiotics (Human/Animal)	Date Published: 12/27/2017
Notes: All Drug and Drug Products	
60 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 12/27/2017
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	Data Duklish - 4, 40/07/0047
63 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 12/27/2017
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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 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 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

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

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

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

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

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

61 - - - - Human and Animal Drugs

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

62 - - - - Human and Animal Drugs

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

63 - - - - Human and Animal Drugs

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

64 - - - - Human and Animal Drugs

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

65 - - - - Human and Animal Drugs

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

66 - - - - Human and Animal Drugs

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

MEXICO

Farma Quimia S.A. de C.V. Date Published : 02/23/2012

Av Andre Marie Ampere No 11 , Parque Industrial Cuamatla , Cuautitlan Izcalli, Mex MEXICO 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

Date Published: 12/27/2017

Date Published: 08/23/2017

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

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 64 - - - - Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products 66 - - - - Human and Animal Drugs Date Published: 02/23/2012 Notes: All Drug Products Jabones Y Productos Especializados SA de CV Date Published: 08/01/2018 Cernicalo 155, Col. La Aurora, Guadalajara, Guadalajara, Jalisco MEXICO 53 J - - -- Personal Cleanliness Date Published: 08/01/2018 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: 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 Date Published: 06/17/2015 Prosintesis S.A. de C.V. 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

Notes: Problems: (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes: Problems: (GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes: Problems: (GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes: Problems: (GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes: Problems: (GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes: Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes: Problems: (GMP) Good Manufacturing Practices

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

Date Published: 12/22/2014

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

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

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

61 - - - - Human and Animal Drugs

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

62 - - - - Human and Animal Drugs

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

63 - - - - Human and Animal Drugs

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

64 - - - - Human and Animal Drugs

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

65 - - - - Human and Animal Drugs

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

66 - - - - Human and Animal Drugs

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

Date Published: 03/28/2014

SOUTH AFRICA

Clover Production 200 Constantia Drive, Weltevreden Park, johannesburg, ZA-GT SOUTH AFRICA

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

Notes: All sterile drug products

56 - - - - Antibiotics (Human/Animal)

Notes: All sterile drug products

60 - - - - Human and Animal Drugs

Notes: All sterile drug products

61 - - - - Human and Animal Drugs

Notes: All sterile drug products

62 - - - - Human and Animal Drugs

Notes: All sterile drug products

63 - - - - Human and Animal Drugs 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

Date Published: 09/17/2010

Date Published: 09/17/2010

SPAIN

Casmara Cosmetics, S.A. Date Published: 10/12/2017 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 Date Published: 10/12/2017 62 - - - - Human and Animal Drugs 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 Date Published: 10/01/2013 62 - - - - Human and Animal Drugs Notes: All drugs and drug products 63 - - - - Human and Animal Drugs Date Published: 10/01/2013 Notes: All drugs and drug products

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

Date Published: 10/01/2013 64 - - - - Human and Animal Drugs 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 Natura Bisse International, Inc. Date Published: 10/28/2016 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

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) Desc: All drug and drug products	Date Published: 09/28/2012
Polaroisin International Co., Ltd.	Date Published : 01/08/2018
Xinzhuang District , NO 173, 10 F; Siyuan Rd. , New Taipei City, TAIWAN 53 L Skin Care Prep Desc: All Drug and Drug Products	Date Published: 01/08/2018
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 Notes: All Drug and Drug Products	Date Published: 01/08/2018
61 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 01/08/2018
62 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 01/08/2018
63 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 01/08/2018
64 Human and Animal Drugs Notes: All Drug and Drug Products	Date Published: 01/08/2018
65 Human and Animal Drugs	Date Published: 01/08/2018

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

Notes: All Drug and Drug Products

Taiwan Three Mast Pharmaceutical Co., Ltd.

3 Jingzhong Rd., Tainan City, TAIWAN

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: 09/04/2012

Date Published: 01/08/2018

Date Published: 09/04/2012

Date Published: 03/10/2015

Date Published: 09/04/2012

THAILAND

PAN RAJDHEVEE GROUP PUBLIC COMPANY LIMITED

50/234-275 MOO 3, LAT SA WAI, LAM LUK KA, Lam Luk Ka, Pathum Thani THAILAND

53 - - - - Cosmetics

Notes: All Drug and Drug Products

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: 03/10/2015

Lam Luk Ka, 73 Moo 12, Pracharaduthid Rd., Bang Phli, Samut Prakan THAILAND

53 - - - - Cosmetics

PCIC Co., Ltd.

Notes: All Drug and Drug Products

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

Date Published: 03/10/2015

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

Notes: All Drug and Drug Products

Date Published: 03/10/2015

Date Published: 11/28/2017

Date Published: 04/16/2013

TRINIDAD & TOBAGO

International Cosmetics Limited Date Published: 11/28/2017

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 53|||||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

Date Published: 02/03/2015

TURKEY

Date Published: 09/10/2009 Ansa

UNKNOWN, Izmit, TURKEY

56 - - - - Antibiotics (Human/Animal) Date Published: 09/10/2009

Mustafa Nevzat Ilac Sanayii, A.S.

Cobancesme Mah., Sanayi Cad., Bahcelievler, Istanbul TURKEY

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

56 - - - - Antibiotics (Human/Animal)

Notes: All drug and drug products GPI=DR; 56[[[[[

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

UNITED ARAB EMIRATES

Digdaga, Airport Road, Ra's al Khaymah, UNITED ARAB EMIRATES

Date Published: 01/31/2012

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

Julphar Gulf Pharmaceutical Industries

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

Seal Sands Road, Middlesborough, Cleveland UNITED KINGDOM 56 - - S -- Antibiotics (Human/Animal), Active Pharm Ingred/Chems for Further Manuf Date Published: 09/10/2009

Notes: All bulk pharmaceuticals 1/26/1996

60 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Date Published: 09/10/2009

Notes: All bulk pharmaceuticals 1/26/1996

61 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Date Published: 09/10/2009

Notes: All bulk pharmaceuticals 1/26/1996

62 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Date Published: 09/10/2009 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 Date Published: 09/10/2009

Notes: All bulk pharmaceuticals 1/26/1996

65 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Date Published: 09/10/2009

Notes: All bulk pharmaceuticals 1/26/1996

66 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Date Published: 09/10/2009

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) Notes: All Drug Products

73 - - - - Anesthesiology

Notes: All Drug Products

74 - - - - Cardiovascular

Notes: All Drug Products

Date Published: 09/10/2009

Date Published: 01/31/2012

Date Published: 05/14/2010

Date Published: 05/14/2010

Date Published: 05/14/2010

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. Date Published: 05/14/2010 Zona Industrial de La Urbina, Calle 6, Centro Empresarial R.S., Caracas, VENEZUELA 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/14/2010 Notes: All Drug Products 56 - - - - Antibiotics (Human/Animal) Date Published: 05/14/2010 Notes: All Drug Products 60 - - - - Human and Animal Drugs Date Published: 05/14/2010 Notes: All Drug Products 61 - - - - Human and Animal Drugs Date Published: 05/14/2010 Notes: All Drug Products 62 - - - - Human and Animal Drugs Date Published: 05/14/2010 Notes: All Drug Products 63 - - - - Human and Animal Drugs Date Published: 05/14/2010 Notes: All Drug Products 64 - - - - Human and Animal Drugs Date Published: 05/14/2010 Notes: All Drug Products 65 - - - - Human and Animal Drugs Date Published: 05/14/2010 Notes: All Drug Products

66 - - - - Human and Animal Drugs

Notes: All Drug Products

Date Published: 05/14/2010