

Import Alert 66-40

1

[FDA Home](#) [Import Program](#) [Import Alerts](#) [Imports Alerts by Number](#) Import Alert

(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: 03/08/2017

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

Radpharm Scientific

57 Oatley Court, Belconnen, AUSTRALIA

Date Published : 09/10/2009

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

Notes:Nexavir

Date Published: 09/10/2009

BELGIUM

Laboratoria Qualiphar NV
Rijksweg 9 , Bornem, Antwerp BELGIUM

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All drug products

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

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

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

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

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

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

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

[illegible]

BRAZIL

Lima & Pergher Ind. Com. Rep Ltda
Av Airton Borges Da Silva 740 , Minas Gerais, BRAZIL

55 - - - - Pharm Necess & Cntr 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

[illegible]

Lima & Pergher Industria e Comercio S/A
Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices

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

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

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

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

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

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

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

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

[illegible]

CANADA

Aleeda Inc
7115 Tomken Rd , Mississauga, ON CANADA

55 ----- Pharm Necess & Cntr 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

[illegible]

66 - - - - Human and Animal Drugs

Date Published: 05/29/2012

Attix Pharmaceuticals Inc.

184 Front St Unit 801 , Toronto, Ontario CANADA

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

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

56 - - - - Antibiotics (Human/Animal)

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

60 - - - - Human and Animal Drugs

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

61 - - - - Human and Animal Drugs

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

62 - - - - Human and Animal Drugs

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

63 - - - - Human and Animal Drugs

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

64 - - - - Human and Animal Drugs

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

65 - - - - Human and Animal Drugs

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

66 - - - - Human and Animal Drugs

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

Date Published : 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Date Published: 02/18/2015

Baxter Healthcare

Unknown Street , Mississauga, ON CANADA

55 R - - 55 Sodium Chloride (Pharmaceutic Necessity - Tonicity Agent)

Desc:0.9% Sodium Chloride Injection USP

65 R - - 12 Potassic Saline (Injection) (Replenisher)

Desc:0.9% Sodium Chloride Injection USP

Date Published : 04/10/2014

Date Published: 04/10/2014

Date Published: 04/10/2014

CMI Cosmetic Manufacturers Inc.

90 Moyal Court , Concord, On CANADA

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

Notes:(GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Notes:(GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

62 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

63 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

64 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

65 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published : 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Date Published: 09/28/2015

Gemini Packaging Ltd.

12071 Jacobson Way , Richmond, British Columbia CANADA

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

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62 - - - - Human and Animal Drugs

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

63 - - - - Human and Animal Drugs

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64 - - - - Human and Animal Drugs

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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 : 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

Date Published: 12/10/2015

International Laboratories (Canada) Ltd.

63 Skyline Cres NE , Calgary, Alberta CANADA

Date Published : 03/14/2014

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

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

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

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

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

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

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

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

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Date Published: 03/14/2014

Pax-All Manufacturing Inc
5000 Howard Business Parkway , Windsor, On CANADA

Date Published : 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

Date Published: 02/23/2012

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

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

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

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

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

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

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

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

CHINA

Attix Pharmaceuticals (Xiamen)
Xiangyue Road , NO. 7 Xinganlu , Shamen, Fujian CHINA

Date Published : 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

Date Published: 05/13/2016

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

Date Published : 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

Date Published: 12/20/2016

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	Date Published: 12/20/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 12/20/2016

Baoying County Fukang Medical Appliance Co., Ltd.
Trade of , Su Zhongbeilu; Baoyingxian , Yangzhou, Jiangsu CHINA

Date Published : 09/20/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products	Date Published: 09/20/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drug and Drug Products	Date Published: 09/20/2016
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016
63 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016
64 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016
65 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016
66 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 09/20/2016

Beijing Shunxin Meihua Bio-technical Co., Ltd.
No 7 Fuqiandongjie , Shunyi District , Shunyiqiu, Beijingshi CHINA

Date Published : 07/22/2014

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
56 - - - - Antibiotics (Human/Animal) Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
60 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
61 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
62 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
63 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
64 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
65 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014
66 - - - - Human and Animal Drugs Notes:All drug products; Firm refused FDA inspection	Date Published: 07/22/2014

Beijing Taiyang Pharmaceutical Industry Co Ltd
NO 1 Shuangqiao (E) Road , Chaoyang, Beijing CHINA

Date Published : 04/29/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
56 - - - - Antibiotics (Human/Animal) Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
60 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
61 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
62 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
63 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
64 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
65 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016
66 - - - - Human and Animal Drugs Notes:All drugs and drug products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/29/2016

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

Date Published : 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/17/2010
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65 - - - - Human and Animal Drugs
Notes:All drug products
66 - - - - Human and Animal Drugs
Notes:All drug products

Date Published: 09/17/2010

Date Published: 09/17/2010

CR Zizhu Pharmaceutical Co Ltd
No. 27, Chaoyang North Rd , Chaoyang District , Beijing, Haidian CHINA

Date Published : 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

Date Published: 03/08/2017

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

Changshu Huagang Pharmaceuticals Co., Ltd
Yuxiang Village, Shanghu Town, , Changshu City, Jiangsu Province CHINA

Date Published : 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

Date Published: 09/30/2013

50 - - - - Color Additiv Food/Drug/Cosmetic
Desc:All drug and drug products
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All drug and drug products
56 - - - - Antibiotics (Human/Animal)
Desc: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

Changzhou SPL Company, Ltd.
West Rd. , Hutang Township, Wujin City , Changzhou City, Jiangsusheng CHINA

Date Published : 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)
Notes:All heparin products 3/10/2008
55 R - - 99 Pharmaceutic Necessities, N.E.C.
Notes:All heparin products 3/10/2008
57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)
Notes:All heparin products 3/10/2008
61 L - - 08 Heparin Sodium (Anti-Coagulant)
Notes:All heparin products 3/10/2008
61 L - - 22 Anti-Coagulant Heparin Sol
Notes:All heparin products 3/10/2008
61 L - - 30 Heparin Calcium (Anti-Coagulant)
Notes:All heparin products 3/10/2008
74 L - - IS Heparin Coating Chemicals,
Notes:All heparin products 3/10/2008
80 N - - ZW Heparin Vascular access flush
Notes:All heparin products 3/10/2008
81 J - - BR Test, Heparin Neutralization
Notes:All heparin products 3/10/2008
81 J - - OX Analyzer, Heparin, Automated
Notes:All heparin products 3/10/2008
81 K - - FF Assay, Heparin
Notes:All heparin products 3/10/2008
88 I - - AZ Heparin

China Resources Sanjiu Medical and Pharmaceutical Co., Ltd.	Date Published : 09/03/2014
No. 1 Guanqing Rd , Guanlan Hi-Tech Park, Longhua District , Shenzhen , Guangdong CHINA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
56 - - - - Antibiotics (Human/Animal) Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
60 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
61 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
62 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
63 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
64 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
65 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014
66 - - - - Human and Animal Drugs Notes:(GMP) Good Manufacturing Practices	Date Published: 09/03/2014

Chongqing Imperial Bio Chem Co	Date Published : 09/10/2009
5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbei Qu, Zhongqingshi CHINA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All APIs 3/16/2009	Date Published: 09/10/2009
56 - - - - Antibiotics (Human/Animal) Notes:All APIs 3/16/2009	Date Published: 09/10/2009
60 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
61 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
62 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
63 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
64 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
65 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
66 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009

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 Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 04/19/2016

Chongqing Paiquiang Agribyproduct Co., Ltd	Date Published : 09/10/2009
158 Gonglongpo , Yudong , Chongqing, CHINA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All APIs 3/16/2009	Date Published: 09/10/2009
56 - - - - Antibiotics (Human/Animal) Notes:All APIs 3/16/2009	Date Published: 09/10/2009
60 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009

61 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
62 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
63 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
64 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
65 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009
66 - - - - Human and Animal Drugs Notes:All APIs 3/16/2009	Date Published: 09/10/2009

Cixi Zhixin Bird Clean-Care Product Co., Ltd.
NO. 137 Balilu , Cixi , Ningbo, Zhejiang CHINA

Date Published : 11/22/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 11/22/2016

Fercy Personal Care Products Co., Ltd
An'Wen Industrial Zone Pan County , Jinhua, Zhejiang CHINA

Date Published : 05/10/2012

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 05/10/2012
56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 05/10/2012
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/10/2012

FriendsUnion(Tianjin) enterprises ltd.
Suites 1808-9 Guohua Building, 857 Dagui , Nan Road, Hexi , Tianjin,China , tianjin, CN-12 CHINA

Date Published : 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug products	Date Published: 09/17/2010
56 - - - - Antibiotics (Human/Animal) Notes:All drug products	Date Published: 09/17/2010
60 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
61 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
62 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
63 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
64 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
65 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
66 - - - - Human and Animal Drugs	Date Published: 09/17/2010

**Guangdong Pharmaceutical Factory #1
91 Fangcun Dadao , Guangzhou, CHINA**

Date Published : 09/10/2009

61 G - - - A-Bacterial Pt. II (Not Antibiotic)
Notes:Active Pharmaceutical Ingredients 12/12/1997
61 H - - - A-Bacterial Pt. III (Not Antibiotic)
Notes:Active Pharmaceutical Ingredients 12/12/1997

Date Published: 09/10/2009

Date Published: 09/10/2009

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

Date Published: 03/14/2016

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/14/2016

Notes:All Drug and Drug Products

Hebei Yuxing Bio-Engineering Co Ltd

Date Published : 07/08/2016

Xicheng District , Ningjin County , Ningjin, 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

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

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

Jinan Jinda Pharmaceutical Chemistry Co., Ltd.
NO. 6121 Longquan Road , Zhangqui City (Jinan), Shandong CHINA

Date Published : 11/25/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio
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: 11/25/2015
Date Published: 11/25/2015
Date Published: 11/25/2015
Date Published: 11/25/2015
Date Published: 11/25/2015
Date Published: 11/25/2015
Date Published: 11/25/2015
Date Published: 11/25/2015

Kunshan Chemicals & Pharmaceutical Factory
No 242 Kun Tai Road , Kunshan City , Jiangsu, CHINA

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:8/30/2007
56 - - - - Antibiotics (Human/Animal)
Notes:8/30/2007
60 - - - - Human and Animal Drugs
Notes:8/30/2007
61 - - - - Human and Animal Drugs
Notes:8/30/2007
62 - - - - Human and Animal Drugs
Notes:8/30/2007
63 - - - - Human and Animal Drugs
Notes:8/30/2007
64 - - - - Human and Animal Drugs
Notes:8/30/2007
65 - - - - Human and Animal Drugs
Notes:8/30/2007
66 - - - - Human and Animal Drugs
Notes:8/30/2007

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

Lumis Global Pharmaceuticals Co. Ltd.
Huishang Mansion Unit 305 , 2 Wudayuan Rd Donghu Ntdz , Wuhan, Hubei CHINA

Date Published : 02/15/2017

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
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
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: 02/15/2017
Date Published: 02/15/2017
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Date Published: 02/15/2017

Nanjing Maohai Biotech Co.
8 Developing Zone , Yaxi Town, Gaochun County , Nanjing Jiangsu Province, CHINA

Date Published : 10/18/2011

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)
Desc:Crude Heparin (Pharmaceutical Necessity)
61 L - - 08 Heparin Sodium (Anti-Coagulant)
Desc:Heparin Sodium (Anti-Coagulant)

Date Published: 10/18/2011
Date Published: 10/18/2011

Nantong Strip Medical Supply Co Ltd
182 Yue Long Nan Road , Building A , Nantong, Jiangsu CHINA

Date Published : 03/27/2013

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.
Sec. C1, Ningbo Eco. & , Tech. Dev. Zone, Beilun District , Ningbo, Zhejiang CHINA

Date Published : 04/08/2011

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.
NO. 27 Luotuo Jiedao Jiushu Fangnanlu , Zhenhai , Ningbo, Zhejiang CHINA

Date Published : 03/05/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 03/05/2013
56 - - - - Antibiotics (Human/Animal)	Date Published: 03/05/2013
60 - - - - Human and Animal Drugs	Date Published: 03/05/2013
61 - - - - Human and Animal Drugs	Date Published: 03/05/2013
62 - - - - Human and Animal Drugs	Date Published: 03/05/2013
63 - - - - Human and Animal Drugs	Date Published: 03/05/2013
64 - - - - Human and Animal Drugs	Date Published: 03/05/2013
65 - - - - Human and Animal Drugs	Date Published: 03/05/2013
66 - - - - Human and Animal Drugs	Date Published: 03/05/2013

Ningbo Zhixin Bird Clean-Care Product Co. Ltd.
137 Bali Road , Zhangqi Town , Zhejiang, CHINA

Date Published : 11/22/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 11/22/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	

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

Date Published: 11/22/2016

**Northeast Pharmaceutical Group Co., Ltd.
37 Zhonggongbeijie , Tiexi , Chenyang, Liaoning CHINA**

Date Published : 09/10/2009

- 45 - - - - Food Additives (Human Use) Date Published: 08/28/2010
Notes:All Pharmaceutical Products; *Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products.; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 46 - - - - Food Additives (Human Use) Date Published: 08/28/2010
Notes:All Pharmaceutical Products *Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Date Published: 08/28/2010
Notes:*Note: The Agency has evidence to support the fact raw materials used in the production of finished drugs are being offered for import into the U.S. as food products; NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 55 - - - - Pharm Necess & Ctnr For Drug/Bio 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
- 56 - - - - Antibiotics (Human/Animal) 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
- 60 - - - - 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: PRODUCT CODE 60S[[]]26 FOR PRODUCT SUCRALFATE IS EXEMPT FROM THIS ALERT. NOTE: Food additives/vitamins for food use are not subject to drug GMP requirements. Only food additives/vitamins manufactured by Northeast General Pharmaceutical Factory which are intended for pharmaceutical use are subject to DWPE
- 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 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
- 63 - - - - 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
- 64 - - - - 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
- 65 - - - - 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
- 66 - - - - 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

**Qinhuangdao Zizhu Pharmaceutical, Co.
No 10, Longhai Road , Economic & Technological Development Zon , Qinhuangdao, Hebei CHINA**

Date Published : 03/08/2017

- 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
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

[illegible]

Shanghai Biochemical And Pharmaceutical Co Ltd
Room A403, No. 494 Zhongxing Road , Shanghai, CHINA

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)
Notes:All heparin products 1/21/2009

55 R - - 99 Pharmaceutic Necessities, N.E.C.
Notes:All heparin products 1/21/2009

57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)
Notes:All heparin products 1/21/2009

61 L - - 08 Heparin Sodium (Anti-Coagulant)
Notes:All heparin products 1/21/2009

61 L - - 22 Anti-Coagulant Heparin Sol
Notes:All heparin products 1/21/2009

61 L - - 30 Heparin Calcium (Anti-Coagulant)
Notes:All heparin products 1/21/2009

74 L - - 15 Heparin Coating Chemicals,
Notes:All heparin products 1/21/2009

80 N - - ZW Heparin Vascular access flush
Notes:All heparin products 1/21/2009

81 J - - BR Test, Heparin Neutralization
Notes:All heparin products 1/21/2009

81 J - - OX Analyzer, Heparin, Automated
Notes:All heparin products 1/21/2009

81 K - - FF Assay, Heparin
Notes:All heparin products 1/21/2009

88 I - - AZ Heparin
Notes:All heparin products 1/21/2009

Date Published : 09/10/2009

[illegible]

Shanghai Huhui Daily Use Chemical Products Co., Ltd.
Pudong District , NO 8 Ludalu , Shanghai, Shanghai CHINA

55 ----- Pharm Necess & Cntr 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 : 04/03/2013

[illegible]

Shanghai Life-Beauty Cosmetics Co., Ltd.
No 2000 Fengxiang Rd , Baoshan District , Shanghai, CHINA

53 E - - 06 Shampoos (Hair Preparations, Non-coloring)
Desc:Dandruff Shampoo
Notes:(GMP) Good Manufacturing Practices

53 F - - 04 Hair Shampoos (Coloring) (Hair Coloring Preparations)
Desc:Dandruff Shampoo
Notes:(GMP) Good Manufacturing Practices

53 J - - 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C.
Desc:Hand Sanitizers
Notes:(GMP) Good Manufacturing Practices

53 J - - - Personal Cleanliness
Desc:Antiperspirants
Notes:(GMP) Good Manufacturing Practices

53 L - - 03 Face,Body,and Hand (excluding Shaving Preparations) (Skin Care Preparations)
Desc:Hand Sanitizers
Notes:(GMP) Good Manufacturing Practices

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drugs;(GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices

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

62 - - - - Human and Animal Drugs

Date Published : 03/28/2014

[illegible]

Notes:All Drugs;(GMP) Good Manufacturing Practices
63 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
64 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
65 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
66 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/28/2014

Date Published: 03/28/2014

Date Published: 03/28/2014

Date Published: 03/28/2014

Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.
1317 Jianchuanlu , Minhang District , Shanghai, Shanghai CHINA

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio
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.
Date Published: 09/10/2009
56 - - - - Antibiotics (Human/Animal)
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.
Date Published: 09/10/2009
60 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009
61 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009
62 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009
63 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009
64 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009
65 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009
66 - - - - Human and Animal Drugs
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.
Date Published: 09/10/2009

Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.
387 Shangqiulu , Shanghai, Shanghai CHINA

Date Published : 09/10/2009

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
55 R - - 99 Pharmaceutic Necessities, N.E.C.
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
61 L - - 08 Heparin Sodium (Anti-Coagulant)
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
61 L - - 22 Anti-Coagulant Heparin Sol
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
61 L - - 30 Heparin Calcium (Anti-Coagulant)
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
74 L - - 15 Heparin Coating Chemicals,
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
80 N - - ZW Heparin Vascular access flush
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
81 J - - BR Test, Heparin Neutralization
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
81 J - - OX Analyzer, Heparin, Automated
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
81 K - - FF Assay, Heparin
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009
88 I - - AZ Heparin
Notes:All Heparin Products 1/21/2009
Date Published: 09/10/2009

Sichuan Pharmaceutical Co., Ltd.
189 Hua Long Road , Pengzhou, Sichuan Province CHINA

Date Published : 05/08/2012

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All drug products
Date Published: 05/08/2012
56 - - - - Antibiotics (Human/Animal)
Notes:All drug products
Date Published: 05/08/2012
60 - - - - Human and Animal Drugs
Date Published: 05/08/2012

Notes:All drug products	
61 - - - - Human and Animal Drugs	Date Published: 05/08/2012
Notes:All drug products	
62 - - - - Human and Animal Drugs	Date Published: 05/08/2012
Notes:All drug products	
63 - - - - Human and Animal Drugs	Date Published: 05/08/2012
Notes:All drug products	
64 - - - - Human and Animal Drugs	Date Published: 05/08/2012
Notes:All drug products	
65 - - - - Human and Animal Drugs	Date Published: 05/08/2012
Notes:All drug products	
66 - - - - Human and Animal Drugs	Date Published: 05/08/2012
Notes:All drug products	

Suzhou No. 4 Pharmaceutical Factory
171 Baiyanglu , Suzhou, Jiangsu CHINA

Date Published : 07/10/2014

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
Tongjing Commercial Plaza Room 920 # 3 , Jiefang Rd , Suzhou, Jiangsu CHINA

Date Published : 10/17/2016

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.
The West of Qiliqiao , Economic Development Zone , Taizhou, Jiangsu Province CHINA

Date Published : 01/15/2013

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 NKY International Ltd.
Suites 1808-9 Guohua Building , Daguan Road, Hexi District , Tianjin, CN-12 CHINA

Date Published : 09/17/2010

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 Notes:All drug products	Date Published: 09/17/2010
64 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
65 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
66 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010

Tianjin Boai Pharmaceutical Co. Ltd
NO. 4 Ronghua Road , Xiqing , Tianjin, Tianjin CHINA

Date Published : 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug products	Date Published: 09/17/2010
56 - - - - Antibiotics (Human/Animal) Notes:All drug products	Date Published: 09/17/2010
60 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
61 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
62 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
63 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
64 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
65 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
66 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010

Tianjin Boai Pharmaceutical Ltd. co.
6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , Tianjin, CN-12 CHINA

Date Published : 09/17/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug products	Date Published: 09/17/2010
56 - - - - Antibiotics (Human/Animal) Notes:All drug products	Date Published: 09/17/2010
60 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
61 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
62 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
63 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
64 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
65 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010
66 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 09/17/2010

Tianjin Zhongan Pharmaceutical Co., Ltd.
Xiqing , 188 Fukang Road , Tianjin, Tianjin CHINA

Date Published : 02/11/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
56 - - - - Antibiotics (Human/Animal) Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
60 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
61 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
62 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
63 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
64 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
65 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016
66 - - - - Human and Animal Drugs Notes:Problem: (GMP) Good Manufacturing Practices	Date Published: 02/11/2016

Xiamen Origin Biotech Co. Ltd.
NO. 7 Xiang Yue Road , Xiamen Torch , Xiamen, Fujian CHINA

Date Published : 05/13/2016

54	----- Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All Drugs and Drug Products Notes:(GMP) Good Manufacturing Practices	Date Published: 05/13/2016
55	----- Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
56	----- Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
60	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
61	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
62	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
63	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
64	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
65	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016
66	----- Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/13/2016

Xinxiang Pharmaceutical Co. Ltd.
NO. 30 Jianshe West Road , Beigandao , Henan, CHINA

53	----- Cosmetics Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
54	----- Vit/Min/Prot/Unconv Diet(Human/Animal) Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
55	----- Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
56	----- Antibiotics (Human/Animal) Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
60	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
61	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
62	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
63	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
64	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
65	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016
66	----- Human and Animal Drugs Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	Date Published: 04/06/2016

Xinxiang Tuoxin Biochemical Co. Ltd
Muye And Deyuan Road Cross Street , Xinxiang City, Henan CHINA

53	----- Cosmetics	Date Published: 04/06/2016
	Notes:All Drug and Drug Products; Notes: Only drug and drug products (i.e. adenosine, choline, uridine, uracil, cytidine, inosine, and all pharmaceutical intermediates) are subject to DWPE under this notice.	
54	----- Vit/Min/Prot/Unconv Diet(Human/Animal)	Date Published: 04/06/2016
	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

Date Published : 08/12/2016

7 Sitong Road , Hanjiang District, Hangji Town , Yangzhou, Jiangsu CHINA

- 53 I - - 01 Dentifrices (Aerosol, Liquid, Toothpastes, Toothpowders), without Fluoride (Oral Hygiene Products)
Desc:All Drug and Drug Products Date Published: 08/12/2016
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)
Desc:All Drug and Drug Products Date Published: 08/12/2016
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

Yunnan Hande Bio-Tech. Co. Ltd.

Date Published : 05/20/2016

NO. 3 Jindingbeilu , Wuhua , Kunming, Yunnan CHINA

- 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 56 - - - - Antibiotics (Human/Animal) Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 60 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 61 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 62 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 63 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 64 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 65 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products
- 66 - - - - Human and Animal Drugs Date Published: 05/20/2016
Notes:All Drug and Drug Products

Zhejiang Bangli Medical Products Co., Ltd

Date Published : 09/09/2016

Huachuan Block , 118 South of Yuegui Road , Yongkang City, Zhejiang CHINA

- 55 - - - - Pharm Necess & Ctnr For Drug/Bio Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
- 56 - - - - Antibiotics (Human/Animal) Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices
- 60 - - - - Human and Animal Drugs Date Published: 09/09/2016

Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 09/09/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	

Zhejiang Casing Animal By-Products Co.,Ltd.	Date Published : 10/18/2011
369 Dong Xing Road , Tonglu Economic Developing District , Hangzhou, Zhejiang Province CN-33 CHINA	
61 L - - 08 Heparin Sodium (Anti-Coagulant)	Date Published: 10/18/2011
Desc:Heparin Sodium (Anti-coagulant)	

Zhejiang Hisoar Pharmaceutical Co. Ltd.	Date Published : 01/20/2016
NO. 100 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 01/20/2016
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	

Zhejiang Hisun Pharmaceutical Co., Ltd.	Date Published : 09/09/2015
46 Waishalu , Jiaojiang , Taizhou, Zhejiang CHINA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	
56 H - S 25 Daunorubicin Hydrochloride (Antitumor), Active Pharm Ingre d/Chems for Further Manuf	Date Published: 02/18/2016
Desc:Daunorubicin Hydrochloride	
Notes:	
	; Problem(s); (GMP) Good Manufacturing Practices
56 - - - - Antibiotics (Human/Animal)	Date Published: 09/09/2015
Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe: Bleomycin 56H[]S10; Capreomycin 56F[]S15;Doxorubicin Hydrochloride 56H[]S24;Mitomycin 56H[]S45;Tazobactam 56Y[]S99;CDER has recommended Sulbactam Sodium, 56M[]J02, be excluded from dwpe under this firm listing;	
60 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe:Granisetron 61T[]S24; CDER has recommended Mesna, 61R[]J22, be excluded from dwpe under this firm listing.	
62 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Cladribine 62I[]S74; Cyclophosphamide 62I[]J15 finished form and API; Cytarabine 62I[]S16;Floxuridine 62V[]S06; Fludarabine 62I[]S79;Ivermectin 62L[]S47	
63 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs;These products are excluded from dwpe:Adenosine 63E[]S18	
64 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 09/09/2015
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices	

Zhejiang Qianfei Enterprise Co. Ltd.	Date Published : 11/24/2015
NO 173 Wulian Road , Yiting Town , Yiwu, 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
Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

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

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

63 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

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

65 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

66 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products; Problems: (GMP) Good Manufacturing Practices

Date Published: 11/24/2015

Date Published: 11/24/2015

Date Published: 11/24/2015

Date Published: 11/24/2015

Date Published: 11/24/2015

Date Published: 11/24/2015

Date Published: 11/24/2015

DENMARK

Leo Pharma A/S Industriparken 55 , Ballerup, DENMARK

Date Published : 03/01/2011

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

Date Published: 03/01/2011

Date Published: 03/01/2011

Leo Pharmaceutical Products A 8 , Copenhagen, DENMARK

Date Published : 03/01/2011

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

Date Published: 03/01/2011

Date Published: 03/01/2011

Leo Pharmaceutical Products Park Alle 26 , Vejen, DENMARK

Date Published : 03/01/2011

61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

61 L - - 99 Anti-Coagulant, N.E.C.
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

Date Published: 03/01/2011

Date Published: 03/01/2011

FRANCE

CISBIO BIOASSAYS 1 route du Parc Marcel Boiteux , Codolet, Gard FRANCE

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Selenomethionine 75 injection

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

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

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

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

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

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

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

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Compagnie Oris Industrie Lpib B.P. #2 91 Gif-Sur-Yvette , Saclay, FRANCE

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Selenomethionine 75 injection

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

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

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

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

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

65 - - - - Human and Animal Drugs
Notes:Selenomethionine 75 Injection

66 - - - - Human and Animal Drugs

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

Ligne St. Barth SAS

Lorient , route de Saline , St Barthelemy, Guadeloupe FRANCE

Date Published : 07/08/2013

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

Societe Chimique Grevis

Avenue De La Paix , Limay, FRANCE

Date Published : 09/10/2009

- 55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 56 - - - - Antibiotics (Human/Animal)
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 60 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 61 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 62 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 63 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 64 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 65 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989
- 66 - - - - Human and Animal Drugs
Notes:Sterile bulk pharmaceutical chemicals 8/10/1989

- Date Published: 09/10/2009
- Date Published: 09/10/2009
- Date Published: 09/10/2009
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- Date Published: 09/10/2009
- Date Published: 09/10/2009
- Date Published: 09/10/2009
- Date Published: 09/10/2009

GERMANY

Heel GmbH , Biologische Heilmittel

Ruhrstr, 14 , Baden, GERMANY

Date Published : 09/10/2009

- 55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 60 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 61 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 62 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 63 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 64 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 65 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.
- 66 - - - - Human and Animal Drugs
Notes:All Injectable Drug Products (4/26/1995) Revised (5/5/2003): All drug products claimed or purported to be sterile and all drug products which by virtue of their intended use should be sterile, i.e. ophthalmic products. Other homeopathic drug products imported from the subject firm and labeled "Not for injection" or "For oral use" are not recommended for DWPE.

- Date Published: 09/10/2009
- Date Published: 09/10/2009
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- Date Published: 09/10/2009
- Date Published: 09/10/2009
- Date Published: 09/10/2009

SANUM-Kehlbeck GmbH & Co. KG

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

Date Published : 07/08/2013

- 50 - - - - Color Additiv Food/Drug/Cosmetic
- 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)

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

[illegible]

Date Published : 05/06/2013

[illegible]

Date Published : 08/31/2013

[illegible]

Date Published : 12/03/2015

53 - - - - Cosmetics	Date Published: 01/07/2016
Desc:All drug products declared as Cosmetic Products	
Notes:The firm has a history of importing some of the following drug products under product code 53: Arthritis Pain Relieving Cream, Pain Relieving Balm, Wok Lok Pain Relieving Oil, Shuang Long Pain Relieving Oil, and Red Flower Oil, Pain Relieving Herbal Oil, Pain Relieving Chi Len Oil, Pain Relieving Po Tong Oil, and Back Pain Relieving Oil. This is not an inclusive list; therefore it is recommended that any products offered for import under product code 53 be thoroughly reviewed to determine if said products are drug products and thus subject to DWPE under this listing.	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 12/03/2015
Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 12/03/2015

Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 12/03/2015
Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	

Luen 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	

Peking Medicine Manufactory	Date Published : 03/04/2014
Unit B, 7/F, Phase 1 , Leader Industry Centre , Tsuen Wan, New Territories HONG KONG	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 03/04/2014
Notes:All Drug Products	
60 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
61 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
62 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
63 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
64 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
65 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	
66 - - - - Human and Animal Drugs	Date Published: 03/04/2014
Notes:All Drug Products	

Seedings	Date Published : 08/31/2013
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	

HUNGARY

Teva Pharmaceutical Works Private Limited Company
Tancsics Mihaly ut 82 , Godollo, Pest HUNGARY

Date Published : 05/27/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe: Amikacin/56D[[]]06; Bleomycin / 56H[[]]10	Date Published: 05/27/2016
60 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
61 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
62 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
63 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
64 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
65 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016
66 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 05/27/2016

INDIA

Aadivighnesh Chem PVT. LTD.
A/7 Badrinath Apartment , Simpoli Road; Borivali West , Mumbai, Maharashtra INDIA

Date Published : 05/05/2014

56 C - - 66 Ceftazidime (Cephalosporins) Desc:Ceftazimide for Injection USP (Sterile)	Date Published: 05/05/2014
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Aarti Drugs Limited
Plot No. E-22, M.I.D.C., Tarapur , Palghar, Maharashtra INDIA

Date Published : 03/23/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
63 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
64 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
65 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
66 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015

Aarti Drugs Ltd
G-60 Boisar MIDC Tarapur , Tal. Palghar, District Thane , Tarapur, Maharashtra INDIA

Date Published : 03/23/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
63 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
64 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
65 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015
66 - - - - Human and Animal Drugs Notes:All Drug and Drug Products; Problem: (GMP)Good Manufacturing Practices	Date Published: 03/23/2015

Akorn India PVT
5/2 5/3 Khasra 5/1 , Paonta Sahib, Himachal Pradesh INDIA

Date Published : 08/21/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
60 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
61 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
62 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
63 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
64 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
65 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015
66 - - - - Human and Animal Drugs Notes:All drugs and drug products Problem: (GMP) Good Manufacturing Practices	Date Published: 08/21/2015

Amsal Chem Pvt. Ltd.

A-1/401-402-403, GIDC , Ankleshwar, Gujarat, INDIA

Date Published : 04/11/2013

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

Badrivishal Chemicals & Pharmaceuticals

Gat No. 29, Village Jambwade (Induri) , Post Sudumbre, Taluka Maval , Dist. Pune, Maharashtra INDIA

Date Published : 12/19/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;(GMP) Good Manufacturing Practices	Date Published: 12/19/2016

Canton Laboratories Pvt. Ltd.

110 A & B Gidc Estate , Makarpura Road , Vadodara, Gujarat INDIA

Date Published : 04/10/2014

54 B - - - Mineral Desc:All Drugs and Drug Products Notes:Problem(s) -- (GMP) Good Manufacturing Practices	Date Published: 04/10/2014
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices	Date Published: 04/10/2014
64 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014
65 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014
66 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products Problem(s) -- (GMP) Good Manufacturing Practices ;	Date Published: 04/10/2014

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 Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Amikacin inj, antibiotic / 56D[]06	Date Published: 07/13/2015
60 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
61 - - - - Human and Animal Drugs 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	Date Published: 07/13/2015
62 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Zoledronic Acid inj, treats/prevents osteoporosis / 62A[]05 Cidofovir inj, treats eye infection in HIV patients / 62V[]21 Carmustine inj, cancer / 62I[]12 Efavirenz / 62V[]24	Date Published: 07/13/2015
63 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
64 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
65 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices	Date Published: 07/13/2015
66 - - - - Human and Animal Drugs Notes:All Drugs All Antibiotics Problem(s): (GMP) Good Manufacturing Practices These products are excluded from dwpe: Haloperidol inj, Antipsychotic / 66M[]98	Date Published: 07/13/2015

Fleming Laboratories Limited48 Temple Rock Enclave , Tarbund Road; Plot No; Bhowanpalli , Secunderabad, Telangana INDIA**Date Published : 04/11/2011**

56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 04/11/2011
73 - - - - Anesthesiology Notes:All Drug Products	Date Published: 04/11/2011
74 - - - - Cardiovascular Notes:All Drug Products	Date Published: 04/11/2011
76 - - - - Dental Notes:All Drug Products	Date Published: 04/11/2011
77 - - - - Ear,Nose And Throat Notes:All Drug Products	Date Published: 04/11/2011
78 - - - - Gastroenterological & Urological Notes:All Drug Products	Date Published: 04/11/2011
79 - - - - General & Plastic Surgery Notes:All Drug Products	Date Published: 04/11/2011
80 - - - - General Hospital/Personal Use Notes:All Drug Products	Date Published: 04/11/2011
84 - - - - Neurological Notes:All Drug Products	Date Published: 04/11/2011
85 - - - - Obstetrical & Gynecological Notes:All Drug Products	Date Published: 04/11/2011
86 - - - - Ophthalmic Notes:All Drug Products	Date Published: 04/11/2011
87 - - - - Orthopedic Notes:All Drug Products	Date Published: 04/11/2011
89 - - - - Physical Medicine Notes:All Drug Products	Date Published: 04/11/2011
90 - - - - Radiological Notes:All Drug Products	Date Published: 04/11/2011

Ipca Laboratories LTD**Date Published : 03/24/2015****1 Pharma Zone , Pithampur, Madhya Pradesh INDIA**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/24/2015
60 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/24/2015
61 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/24/2015
62 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices This product is excluded from dwpe: Hydroxychloroquine Sulfate/62L[]29	Date Published: 03/24/2015
63 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/24/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/24/2015
65 - - - - Human and Animal Drugs	Date Published: 03/24/2015

Notes:All Drugs;(GMP) Good Manufacturing Practices
66 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 03/24/2015

Ipca Laboratories Limited

Plot No. 65 and 99, Danudyog , Ind. Estate, Piparia , Silvasa (D and NH), INDIA

Date Published : 03/24/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drugs;(GMP) Good Manufacturing Practices;
Date Published: 03/24/2015
60 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
Date Published: 03/24/2015
61 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
Date Published: 03/24/2015
62 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices These products are excluded from dwpe: Hydroxychloroquine Sulfate/62L[]29
Date Published: 03/24/2015
63 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices; These products are excluded from dwpe: Propranolol Hydrochloride/63E[]13
Date Published: 03/24/2015
64 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
Date Published: 03/24/2015
65 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
Date Published: 03/24/2015
66 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
Date Published: 03/24/2015

Ipca Laboratories Limited

Village Sejavta , Ratlam, Madhya Pradesh INDIA

Date Published : 01/22/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices;
Date Published: 01/22/2015
56 - - - - Antibiotics (Human/Animal)
Notes:All Antibiotics;Problem(s): (GMP) Good Manufacturing Practices
Date Published: 01/22/2015
60 - - - - Human and Animal Drugs
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices
Date Published: 01/22/2015
61 - - - - Human and Animal Drugs
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices;These products are excluded from dwpe:Sulfamethoxazole/ 61G[]57 Trimethoprim/61H[]03 Ondansetron/61T[]26, 61T[]27, 61T[]28;This product is excluded from DWPE: Chloroquine Phosphate API/61A[]06
Date Published: 01/22/2015
62 - - - - Human and Animal Drugs
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Hydroxychloroquine Sulfate/62L[]29
Date Published: 01/22/2015
63 - - - - Human and Animal Drugs
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices:These products are excluded from dwpe: Propranolol Hydrochloride/63E[]13
Date Published: 01/22/2015
64 - - - - Human and Animal Drugs
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from DWPE: Furosemide/64BQS24
Date Published: 01/22/2015
65 - - - - Human and Animal Drugs
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices
Date Published: 01/22/2015
66 - - - - Human and Animal Drugs
Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices
Date Published: 01/22/2015

Kamud Drugs Pvt. Ltd.

N-6 & 8 MIDC, Kupwad , Taluka Miraj , Sangli, Maharashtra INDIA

Date Published : 07/10/2013

50 - - - - Color Additiv Food/Drug/Cosmetic
Notes:All drug and drug products
Date Published: 07/10/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
Notes:All drug and drug products
Date Published: 07/10/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All drug and drug products
Date Published: 07/10/2013
56 - - - - Antibiotics (Human/Animal)
Notes:All drug and drug products
Date Published: 07/10/2013
60 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013
61 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013
62 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013
63 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013
64 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013
65 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013
66 - - - - Human and Animal Drugs
Notes:All drug and drug products
Date Published: 07/10/2013

Konduskar Laboratories Pvt Ltd	Date Published : 07/10/2013
T-47 Kagel Hatkanangale Five Star, MIDC , Talandage (Village), Tal: Kagal , Maharashtra State, INDIA	
50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drug and drug products	Date Published: 07/10/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drug and drug products	Date Published: 07/10/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug and drug products	Date Published: 07/10/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drug and drug products	Date Published: 07/10/2013
60 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013
61 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013
62 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013
63 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013
64 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013
65 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013
66 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 07/10/2013

Marck Biosciences Ltd.	Date Published : 03/12/2014
Plot No. 876, N.H. - 8 , Vill: Hariyala, Tal: Matar , Kheda, Gujarat INDIA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 03/12/2014
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/12/2014

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 Notes:All Drug and Drug Products	Date Published: 10/14/2015
60 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015
61 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015
62 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015
63 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015
64 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015
65 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015
66 - - - - Human and Animal Drugs Notes:All Drug and Drug Products	Date Published: 10/14/2015

Micro Labs Limited	Date Published : 09/19/2014
S - 155 Plot No , Verna Industrial Estate , Vasco Da Gama, Goa INDIA	
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
60 - - - - Human and Animal Drugs Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
61 - - - - Human and Animal Drugs Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
62 - - - - Human and Animal Drugs Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
63 - - - - Human and Animal Drugs	Date Published: 09/19/2014

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: 09/19/2014

Date Published: 09/19/2014

Date Published: 09/19/2014

Nivedita Chemicals P ITd
A14 MIDC Andheri East , Mumbai, IN-MH INDIA

Date Published : 11/23/2011

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Chlorpheniramine maleate
60 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic)
Desc:Chlorpheniramine maleate
61 X - - 29 Pyrilamine Maleate (Anti-Histaminic)
Desc:Chlorpheniramine maleate
61 X - - 29 Pyrilamine Maleate (Anti-Histaminic)
Desc:Pyrilamine maleate Pyrilamine maleate USP
61 X - - 99 Anti-Histaminic N.E.C.
Desc:Pyrilamine maleate Pyrilamine maleate USP
61 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
62 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
63 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
64 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
65 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
66 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Nivedita Chemicals Pvt. Ltd.
A - 14 Maharashtra , M i d C; Andheri East , Mumbai, Maharashtra INDIA

Date Published : 11/23/2011

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Chlorpheniramine maleate
60 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic)
Desc:Chlorpheniramine maleate
61 X - - 29 Pyrilamine Maleate (Anti-Histaminic)
Desc:Pyrilamine maleate Pyrilamine maleate USP
61 X - - 29 Pyrilamine Maleate (Anti-Histaminic)
Desc:Chlorpheniramine maleate
61 X - - 99 Anti-Histaminic N.E.C.
Desc:Pyrilamine maleate Pyrilamine maleate USP
61 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
62 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
63 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
64 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
65 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate
66 - - - - Human and Animal Drugs
Notes:Chlorpheniramine maleate

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Date Published: 11/23/2011

Pan Drugs Limited
192 G I D C Makarpura Industrial Estate , M I Estate , Vadodara, Gujarat INDIA

Date Published : 12/08/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drugs;(GMP) Good Manufacturing Practices
56 - - - - Antibiotics (Human/Animal)
Notes:All Antibiotics;(GMP) Good Manufacturing Practices
60 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
61 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices
62 - - - - Human and Animal Drugs
Notes:All Drugs;(GMP) Good Manufacturing Practices

Date Published: 12/08/2015

Date Published: 12/08/2015

Date Published: 12/08/2015

Date Published: 12/08/2015

Date Published: 12/08/2015

63 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
65 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015
66 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 12/08/2015

Pan Drugs Ltd.

167-168, GIDC Nandesari Ind. Estate , Nandesari, Vadodara, Gujarat INDIA

Date Published : 05/05/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
56 - - - - Antibiotics (Human/Animal) Notes:All Antibiotics;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
60 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
61 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
62 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
63 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
65 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015
66 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 05/05/2015

Polydrug Laboratories Pvt. Ltd.

Plot N37, Ambernath Industrial Area , Anand Nagar MIDC , Mumbai, Maharashtra INDIA

Date Published : 09/11/2015

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All Drugs Notes:Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
60 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
61 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
62 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
63 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
64 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
65 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015
66 - - - - Human and Animal Drugs Notes:All Drugs;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 09/11/2015

RPG Life Sciences Limited

3102/A G.I.D.C. Estate , 393002 , Ankleshwar, Gujarat INDIA

Date Published : 06/11/2013

50 - - - - Color Additiv Food/Drug/Cosmetic	Date Published: 06/11/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 06/11/2013
56 - - - - Antibiotics (Human/Animal)	Date Published: 06/11/2013
60 - - - - Human and Animal Drugs	Date Published: 06/11/2013
61 - - - - Human and Animal Drugs	Date Published: 06/11/2013
62 - - - - Human and Animal Drugs	Date Published: 06/11/2013
63 - - - - Human and Animal Drugs	Date Published: 06/11/2013
64 - - - - Human and Animal Drugs	Date Published: 06/11/2013
65 - - - - Human and Animal Drugs	Date Published: 06/11/2013
66 - - - - Human and Animal Drugs	Date Published: 06/11/2013

RPG Life Sciences Limited

25, M.I.D.C. Land, Thane-Belapur Road , Thane, Maharashtra INDIA

Date Published : 06/10/2013

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

Date Published: 06/10/2013
Date Published: 06/10/2013
Date Published: 06/10/2013
Date Published: 06/10/2013

Sal Pharma

1-7-176 Bakaram , Hyderabad, Andhra 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

Date Published : 02/15/2017

Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017
Date Published: 02/15/2017

Sentiss Pharma Pvt. Ltd.

Village Khera Nihla , Tehsil Nalargarh , District Solan, Himachal Pradesh INDIA

50 - - - - Color Additiv Food/Drug/Cosmetic
55 - - - - Pharm Necess & Ctnr For Drug/Bio
56 - - - - Antibiotics (Human/Animal)
60 - - - - Human and Animal Drugs
61 - - - - Human and Animal Drugs
62 - - - - Human and Animal Drugs
63 - - - - Human and Animal Drugs
64 - - - - Human and Animal Drugs
65 - - - - Human and Animal Drugs
66 - - - - Human and Animal Drugs
86 - - - - Ophthalmic

Date Published : 06/20/2013

Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013
Date Published: 06/20/2013

Smruthi Organics Limited

Plot No. A-27, MIDC, Chincholi , Solapur District, Maharashtra, Maharashtra State INDIA

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 : 06/03/2013

Date Published: 06/03/2013
Date Published: 06/03/2013
Date Published: 06/03/2013
Date Published: 06/03/2013
Date Published: 06/03/2013
Date Published: 06/03/2013
Date Published: 06/03/2013
Date Published: 06/03/2013

Sri Krishna Pharmaceuticals Ltd. - Unit II

A-35, IDA, Nacharam , Hyderabad, Andhra Pradesh, INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drugs
60 - - - - Human and Animal Drugs
Notes:All Drugs
61 - - - - Human and Animal Drugs
Notes:All Drugs
62 - - - - Human and Animal Drugs
Notes:All Drugs
63 - - - - Human and Animal Drugs
Notes:All Drugs
64 - - - - Human and Animal Drugs
Notes:All Drugs
65 - - - - Human and Animal Drugs
Notes:All Drugs;This product is excluded from dwpe: Sodium Phenylbutyrate granules/65C[]09
66 - - - - Human and Animal Drugs
Notes:All Drugs

Date Published : 08/13/2015

Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015
Date Published: 08/13/2015

Srikem Laboratories Pvt. Ltd.

Plot No. 17/24, MIDC Taloja , Navi Mumbai, Maharashtra INDIA

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

Date Published : 07/06/2016

Date Published: 07/06/2016

Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
56 - - - - Antibiotics (Human/Animal)	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
62 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
63 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
64 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
65 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 07/06/2016
Notes:All Drugs and Drug Products; Problem: (GMP) Good Manufacturing Practices	

Stericon Pharma Pvt. Ltd.

Date Published : 01/13/2011

No. 9, Sub Layout Of Plot 9 , 1st Phase Bommasandra Ind. Area , Bangalore, Karnataka INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 01/13/2011
Notes:All Drug Products	
60 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	
61 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	
62 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	
63 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	
64 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	
65 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	
66 - - - - Human and Animal Drugs	Date Published: 01/13/2011
Notes:All Drug Products	

Sun Pharmaceutical Industries (prev. Ranbaxy)

Date Published : 09/10/2009

3 Industrial Area No , Aakya, 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	

Sun Pharmaceutical Industries (prev. Ranbaxy)

Date Published : 09/10/2009

Tehsil , Simour District , Paonta Sahib, Himachal 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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 contact 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

Date Published: 03/12/2014

Desc:All Human Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/12/2014

Desc:All Human Drug Products

Sun Pharmaceutical Industries, Inc

Date Published : 09/13/2013

SEZ Unit 1, Plot No. A-41 , Industrial Area Phase VIII-A, SAS Nagar , Mohali, Punjab INDIA

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

Date Published: 09/13/2013

Desc:All drugs and drug products

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

Date Published: 09/13/2013

Desc:All drugs and drug products

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

Date Published: 09/13/2013

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/13/2013

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

61 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

62 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

63 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

64 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

65 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

66 - - - - Human and Animal Drugs

Date Published: 09/13/2013

Notes:All drugs and drug products

Unique Chemicals

Date Published : 06/28/2013

Shiv Mahape Gansoli , Thane Belapur Road , Navi Mumbai, Maharashtra INDIA

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

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 06/28/2013

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013

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 Desc:All drugs and drug products	Date Published: 06/28/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 06/28/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013

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 Desc:All drugs and drug products	Date Published: 06/28/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 06/28/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drugs and drug products	Date Published: 06/28/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 06/28/2013

Vikshara Trading & Investments Ltd.

Date Published : 02/08/2017

Odhav Road , Ahmedabad, Gujarat INDIA

53 - - - - Cosmetics Notes:All Drug and Drug Products;For Industry Code 53, only drug and drug products are subject to DWPE under this notice.	Date Published: 02/08/2017
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products;.	Date Published: 02/08/2017
56 - - - - Antibiotics (Human/Animal) Notes:All Drug and Drug Products;.	Date Published: 02/08/2017
60 - - - - Human and Animal Drugs	Date Published: 02/08/2017

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: 02/08/2017
Date Published: 02/08/2017
Date Published: 02/08/2017
Date Published: 02/08/2017
Date Published: 02/08/2017
Date Published: 02/08/2017

Wockhardt Limited
L-1, MIDC Area, Jalgaon Road 43 , Chikalthana , Aurangabad,
Maharashtra INDIA

Date Published : 11/26/2013

50 - - - - Color Additiv Food/Drug/Cosmetic
Desc:All Drug and Drug Products
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drug and Drug Products
56 - - - - Antibiotics (Human/Animal)
Desc: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; * Notes: These products are excluded from DWPE: Enalapril Maleate (Antihypertensive - part II)
(62OCA28, 62OCS28)
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: 09/28/2016
Date Published: 11/26/2013
Date Published: 09/28/2016
Date Published: 11/26/2013
Date Published: 11/26/2013
Date Published: 11/26/2013
Date Published: 11/26/2013
Date Published: 11/26/2013
Date Published: 11/26/2013

Wockhardt Limited
H-14/2 Plot , Biotech Park , Aurangabad, Maharashtra INDIA

Date Published : 05/22/2013

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 Except -- Enalapril Maleate (62O[]28)
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;

Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013
Date Published: 05/22/2013

Wockhardt, Ltd.
Plot 138 GIDC Industrial , Bulk Drug Division, Dist. Bharuch , Ankleshwar, INDIA

Date Published : 08/05/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drug and Drug Products
56 - - - - Antibiotics (Human/Animal)
Notes:All Drug and Drug Products;The following drug is excluded from DWPE; Ceftriaxone Sodium / 56C[]70 ;
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

Date Published: 08/05/2016
Date Published: 08/05/2016
Date Published: 08/05/2016
Date Published: 08/05/2016
Date Published: 08/05/2016
Date Published: 08/05/2016

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: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Yag Mag Labs Private Limited

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

Date Published : 09/13/2011

60 L - - 69 Tramadol HCl (Analgesic)
Desc:Tramadol HCl (Analgesic)

Date Published: 09/13/2011

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

Date Published: 09/13/2011

64 H - - 02 Guaifenesin (Expectorant)
Desc:Guaifensein (Expectorant)

Date Published: 09/13/2011

ITALY

Topchem SRL

Viale Andrea Doria 17 , Milano, MI ITALY

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

Date Published: 09/10/2009

66 - - - - Human and Animal Drugs
Notes:All bulk drugs 8/4/1992

Date Published: 09/10/2009

JAMAICA

P.A. Benjamin Manufacturing Co., Ltd.

95-97 East Street , Kingston, JM-01 JAMAICA

Date Published : 08/29/2012

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 Obata Kanra-machi , Kanra-gun, Gunma-ken JAPAN

Date Published : 02/13/2013

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

Date Published: 02/13/2013

60 - - - - Human and Animal Drugs
Notes:All Drugs Products

Date Published: 02/13/2013

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

Date Published: 02/13/2013

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

Date Published: 02/13/2013

63 - - - - Human and Animal Drugs
Notes:All Drugs Products

Date Published: 02/13/2013

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

Date Published: 02/13/2013

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

Date Published: 02/13/2013

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

Date Published: 02/13/2013

Kanebo Cosmetics Inc.

Odawara-shi Kanagawa 28 , Kotobuki-Cho , Odawara, Kanagawa JAPAN

Date Published : 05/06/2013

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

Date Published: 05/06/2013

56 - - - - Antibiotics (Human/Animal)
 60 - - - - Human and Animal Drugs
 61 - - - - Human and Animal Drugs
 62 - - - - Human and Animal Drugs
 63 - - - - Human and Animal Drugs
 64 - - - - Human and Animal Drugs
 65 - - - - Human and Animal Drugs
 66 - - - - Human and Animal Drugs

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

KOREA, REPUBLIC OF (SOUTH)

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
 Desc:All drugs and drug products
 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
 Desc:All drugs and drug products
 55 - - - - Pharm Necess & Ctnr For Drug/Bio
 Notes:All drugs and drug products
 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
 80 - - - - General Hospital/Personal Use
 Desc:All Drugs and Drug Products
 81 - - - - Hematology
 Desc:All drugs and drug products
 89 - - - - Physical Medicine
 Desc:All drugs and drug products

Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013
 Date Published: 09/06/2013
 Date Published: 09/04/2013
 Date Published: 09/04/2013

LG Life Sciences

Date Published : 05/06/2013

129 Seokam-ro , Iksan Plant , Iksan-si, Jeollabuk-do, KOREA, REPUBLIC OF (SOUTH)

50 - - - - Color Additiv Food/Drug/Cosmetic
 53 - - - - Cosmetics
 55 - - - - Pharm Necess & Ctnr For Drug/Bio
 56 - - - - Antibiotics (Human/Animal)
 60 - - - - Human and Animal Drugs
 61 - - - - Human and Animal Drugs
 62 - - - - Human and Animal Drugs
 63 - - - - Human and Animal Drugs
 64 - - - - Human and Animal Drugs
 65 - - - - Human and Animal Drugs
 66 - - - - Human and Animal Drugs
 80 - - - - General Hospital/Personal Use

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

MEXICO

Compania Internacional de Comercio, S.A. P.I. de C.V.

Date Published : 05/17/2012

Calle Monzon (Juarez) No. 184 , Iztapalapa, Col. CERRO DE LA ESTRELLA , Mexico, Distrito Federal MEXICO

55 - - - - Pharm Necess & Ctnr For Drug/Bio
 56 - - - - Antibiotics (Human/Animal)
 60 - - - - Human and Animal Drugs
 61 - - - - Human and Animal Drugs
 62 - - - - Human and Animal Drugs
 63 - - - - Human and Animal Drugs
 64 - - - - Human and Animal Drugs
 65 - - - - Human and Animal Drugs
 66 - - - - Human and Animal Drugs

Date Published: 05/17/2012
 Date Published: 05/17/2012
 Date Published: 05/17/2012
 Date Published: 05/17/2012
 Date Published: 05/17/2012
 Date Published: 05/17/2012
 Date Published: 05/17/2012
 Date Published: 05/17/2012

Farma Quimica 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)

Date Published: 02/23/2012
 Date Published: 02/23/2012

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

Date Published: 02/23/2012
Date Published: 02/23/2012
Date Published: 02/23/2012
Date Published: 02/23/2012
Date Published: 02/23/2012
Date Published: 02/23/2012
Date Published: 02/23/2012

Prosintesis S.A. de C.V.

Avenida Educacion s/n , Pueblo Santa Maria Mazatla , Jilotzingo, Mexico MEXICO

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Problems: (GMP) Good Manufacturing Practices
56 - - - - Antibiotics (Human/Animal)
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

Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015
Date Published: 06/17/2015

NEW ZEALAND

Jaychem Industries Ltd

3 Kordel Place , East Tamaki , Auckland, NEW ZEALAND

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drug and Drug Products
56 - - - - Antibiotics (Human/Animal)
Notes:All Drug and Drug Products
60 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products
61 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products
62 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products
63 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products
64 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products
65 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products
66 - - - - Human and Animal Drugs
Notes:All Drug and Drug Products

Date Published : 12/22/2014

Date Published: 12/22/2014
Date Published: 12/22/2014
Date Published: 12/22/2014
Date Published: 12/22/2014
Date Published: 12/22/2014
Date Published: 12/22/2014
Date Published: 12/22/2014
Date Published: 12/22/2014
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

Date Published : 03/28/2014

Date Published: 03/28/2014
Date Published: 03/28/2014
Date Published: 03/28/2014
Date Published: 03/28/2014
Date Published: 03/28/2014
Date Published: 03/28/2014

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

Date Published: 03/28/2014

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

Date Published: 09/17/2010

56 - - - - Antibiotics (Human/Animal)
Notes:All sterile drug products

Date Published: 09/17/2010

60 - - - - Human and Animal Drugs
Notes:All sterile drug products

Date Published: 09/17/2010

61 - - - - Human and Animal Drugs
Notes:All sterile drug products

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

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

Date Published: 09/17/2010

SPAIN

Dysers S.A.L.

Depositos 12 , Segovia, SPAIN

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

63 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

64 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

65 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

66 - - - - Human and Animal Drugs
Notes:Non-sterile bulk drug products 5/1/1992

Date Published: 09/10/2009

Jabones Pardo S.A.

Calle Sierra Nevada 1 , Fuenlabrada, Madrid SPAIN

53 - - - - Cosmetics
Desc:All drugs and drug products

Date Published: 10/01/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All drugs and drug products

Date Published: 10/01/2013

56 - - - - Antibiotics (Human/Animal)
Desc:All drugs and drug products

Date Published: 10/01/2013

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

Date Published: 10/01/2013

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

Date Published: 10/01/2013

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

Date Published: 10/01/2013

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

Date Published: 10/01/2013

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

Date Published: 10/01/2013

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

Date Published: 10/01/2013

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

Date Published: 10/01/2013

Natura Bisse International S.A.**Date Published : 10/28/2016****Parque Tecnológico del Valles , Artesans , , 12 Cerdanyola,****Barcelona SPAIN**

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

Date Published: 10/28/2016

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

56 - - - - Antibiotics (Human/Animal)

Date Published: 10/28/2016

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

60 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

61 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

62 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

63 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

64 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

65 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

66 - - - - Human and Animal Drugs

Date Published: 10/28/2016

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

TAIWAN**Beanne Chemical Co.****Date Published : 09/28/2012****No. 28, Lane 456, Fongihou Road , Shengang District , Taichung City, TAIWAN**

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

Date Published: 09/28/2012

Desc:All drug and drug products

53 - - - - Cosmetics

Date Published: 09/28/2012

Desc:All drug and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/28/2012

Desc:All drug and drug products

Taiwan Three Mast Pharmaceutical Co., Ltd.**Date Published : 09/04/2012****3 Jingzhong Rd. , Tainan City, TAIWAN**

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

Date Published: 09/04/2012

60 - - - - Human and Animal Drugs

Date Published: 09/04/2012

61 - - - - Human and Animal Drugs

Date Published: 09/04/2012

62 - - - - Human and Animal Drugs

Date Published: 09/04/2012

63 - - - - Human and Animal Drugs

Date Published: 09/04/2012

64 - - - - Human and Animal Drugs

Date Published: 09/04/2012

65 - - - - Human and Animal Drugs

Date Published: 09/04/2012

66 - - - - Human and Animal Drugs

Date Published: 09/04/2012

THAILAND**PAN RAJDHEVEE GROUP PUBLIC COMPANY LIMITED****Date Published : 03/10/2015****50/234-275 MOO 3, LAT SA WAI, LAM LUK KA , Lam Luk Ka, Pathum Thani THAILAND**

53 - - - - Cosmetics

Date Published: 03/10/2015

Notes:All Drug and Drug Products

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

Date Published: 03/10/2015

Notes:All Drug and Drug Products

56 - - - - Antibiotics (Human/Animal)

Date Published: 03/10/2015

Notes:All Drug and Drug Products

60 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

61 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

62 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

63 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

64 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

65 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

66 - - - - Human and Animal Drugs

Date Published: 03/10/2015

Notes:All Drug and Drug Products

PCIC Co., Ltd.**Date Published : 03/10/2015****Lam Luk Ka , 73 Moo 12, Pracharaduthid Rd. , Bang Phli, Samut Prakan THAILAND**

53 - - - - Cosmetics

Date Published: 03/10/2015

Notes:All Drug and Drug Products

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

Date Published: 03/10/2015

Notes:All Drug and Drug Products

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

Date Published: 03/10/2015
Date Published: 03/10/2015
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Date Published: 03/10/2015
Date Published: 03/10/2015

TUNISIA

Unite de Fabrication de Medicaments SA
Zone Industrielle , Kalaa El Kebira , Sousse, Sousse TUNISIA

Date Published : 02/03/2015

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

Date Published: 02/03/2015

TURKEY

Ansa
UNKNOWN , Izmit, TURKEY

Date Published : 09/10/2009

56 - - - - Antibiotics (Human/Animal)

Date Published: 09/10/2009

Mustafa Nevzat Ilac Sanayii, A.S.
Cobancesme Mah. , Sanayi Cad. , Bahcelievler, Istanbul

Date Published : 04/16/2013

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

UNITED ARAB EMIRATES

Julphar Gulf Pharmaceutical Industries
Digdaga , Airport Road , Ra's al Khaymah, UNITED ARAB EMIRATES

Date Published : 01/31/2012

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All Drug Products
56 - - - - Antibiotics (Human/Animal)
Notes:All Drug Products
60 - - - - Human and Animal Drugs
Notes:All Drug Products
61 - - - - Human and Animal Drugs
Notes:All Drug Products
62 - - - - Human and Animal Drugs
Notes:All Drug Products
63 - - - - Human and Animal Drugs
Notes:All Drug Products
64 - - - - Human and Animal Drugs
Notes:All Drug Products
65 - - - - Human and Animal Drugs
Notes:All Drug Products
66 - - - - Human and Animal Drugs
Notes:All Drug Products

Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012
Date Published: 01/31/2012

UNITED KINGDOM

Fresenius Kabi Oncology Plc
Lion Court , Farnham Road , Bordon, Hampshire UNITED KINGDOM

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes:All finished pharmaceutical products
56 - - - - Antibiotics (Human/Animal)
Notes:All finished pharmaceutical products
60 - - - - Human and Animal Drugs
Notes:All finished pharmaceutical products

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

61 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products	Date Published: 09/10/2009
62 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products	Date Published: 09/10/2009
63 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products	Date Published: 09/10/2009
64 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products	Date Published: 09/10/2009
65 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products	Date Published: 09/10/2009
66 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products	Date Published: 09/10/2009

Hampshire Chemicals, Ltd.

Seal Sands Road , Middlesborough, Cleveland UNITED KINGDOM

Date Published : 09/10/2009

56 - - S -- Antibiotics (Human/Animal), Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
60 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
61 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
62 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
63 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
64 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
65 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
66 - - S -- Human and Animal Drugs, Active Pharm Ingred/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009

VENEZUELA

LABORATORIOS LO OFTALMI CA

CTO. EMPRESARIAL "RS", CALLE 6 , ZONA INDUSTRIAL LA URBINA , Caracas, VE-NOTA VENEZUELA

Date Published : 05/14/2010

56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 05/14/2010
73 - - - - Anesthesiology Notes:All Drug Products	Date Published: 05/14/2010
74 - - - - Cardiovascular Notes:All Drug Products	Date Published: 05/14/2010
76 - - - - Dental Notes:All Drug Products	Date Published: 05/14/2010
77 - - - - Ear,Nose And Throat Notes:All Drug Products	Date Published: 05/14/2010
78 - - - - Gastroenterological & Urological Notes:All Drug Products	Date Published: 05/14/2010
79 - - - - General & Plastic Surgery Notes:All Drug Products	Date Published: 05/14/2010
80 - - - - General Hospital/Personal Use Notes:All Drug Products	Date Published: 05/14/2010
84 - - - - Neurological Notes:All Drug Products	Date Published: 05/14/2010
85 - - - - Obstetrical & Gynecological Notes:All Drug Products	Date Published: 05/14/2010
86 - - - - Ophthalmic Notes:All Drug Products	Date Published: 05/14/2010
87 - - - - Orthopedic Notes:All Drug Products	Date Published: 05/14/2010
89 - - - - Physical Medicine Notes:All Drug Products	Date Published: 05/14/2010
90 - - - - Radiological Notes:All Drug Products	Date Published: 05/14/2010

Laboratorios L.O. Oftalmi, C.A.

Zona Industrial de La Urbina , Calle 6, Centro Empresarial R.S. , Caracas, VENEZUELA

Date Published : 05/14/2010

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 05/14/2010
56 - - - - Antibiotics (Human/Animal) Notes:All Drug Products	Date Published: 05/14/2010
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010

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

Date Published: 05/14/2010

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

[Email FDA](#)

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