

U.S. Food & Drug Administration

Import Alert 66-40

1

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(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: 08/05/2016

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****Date Published : 01/18/2011**

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

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

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

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

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

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

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

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

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

Date Published: 01/18/2011

BRAZIL**Lima & Pergher Ind. Com. Rep Ltda
Av Airon Borges Da Silva 740 , Minas Gerais, BRAZIL****Date Published : 07/15/2016**

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

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

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

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

**Lima & Pergher Industria e Comercio S/A
Rua Engenheiro Diniz 2069, B. Martins , Uberlandia, Minas Gerais BRAZIL****Date Published : 07/15/2016**

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

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66 - - - - Human and Animal Drugs
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Date Published: 07/15/2016

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Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

Date Published: 07/15/2016

CANADA**Aleeda Inc
7155 Tomken Rd , Mississauga, ON CANADA****Date Published : 05/29/2012**

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

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

Date Published: 05/29/2012

66 - - - - Human and Animal Drugs

**Attix Pharmaceuticals Inc.
184 Front St Unit 801 , Toronto, Ontario CANADA**

Date Published : 02/18/2015

- 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
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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
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- Date Published: 02/18/2015
- Date Published: 02/18/2015
- Date Published: 02/18/2015

**Baxter Healthcare
Unknown Street , Mississauga, ON CANADA**

Date Published : 04/10/2014

- 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

**CMI Cosmetic Manufacturers Inc.
90 Moyal Court , Concord, On CANADA**

Date Published : 09/28/2015

- 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
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- Date Published: 09/28/2015
- Date Published: 09/28/2015

**Gemini Packaging Ltd.
12071 Jacobson Way , Richmond, British Columbia CANADA**

Date Published : 12/10/2015

- 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
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- 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: 12/10/2015
- Date Published: 12/10/2015
- Date Published: 12/10/2015
- Date Published: 12/10/2015
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- 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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

Date Published: 03/14/2014

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

**Pax-All Manufacturing Inc.
7115 Tomken Road , Mississauga, ON CANADA**

Date Published : 02/23/2012

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

Date Published: 02/23/2012

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

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
Desc:All Drugs and Drug Products

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

Date Published: 05/13/2016

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

**BOAI NKY PHARMACEUTICALS LTD.
Suites 1808-9 Guohua Building, 857 Dagu- , Nan Road, Hexi , Tianjin,China , tianjin, CN-12 CHINA**

Date Published : 09/17/2010

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
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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

Beijing Lunarsun Pharmaceutical Co., Ltd
C1 802 Yangguang Plaza, No. 68 Anli Rd , Chaoyang Dis. , Beijing, CHINA

Date Published : 04/19/2016

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

Date Published: 04/19/2016

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

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

Date Published : 07/22/2014

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

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

Date Published : 04/29/2016

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
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Date Published: 04/29/2016

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Date Published: 04/29/2016

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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

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

Date Published : 09/17/2010

Date Published: 09/17/2010

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

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

Boai NKY Pharmaceuticals Ltd.**No.1888 Wenhua Road , Boai , Jiaozuo, Henansheng CHINA****Date Published : 05/18/2015**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
60 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
61 - - - - Human and Animal Drugs	Date Published: 05/18/2015
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63 - - - - Human and Animal Drugs	Date Published: 05/18/2015
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65 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	
66 - - - - Human and Animal Drugs	Date Published: 05/18/2015
Notes:All drug and drug products;(GMP) Good Manufacturing Practices	

Boai NKY Pharmaceuticals Ltd.**No. 9 Zhongshan Road , Boai County , Jiaozuo, Henan 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
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65 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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66 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	

Boai Xinda Food Co., Ltd.**The North Of Dong Wang He, Xiaojing , Boai, Henansheng 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
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61 - - - - Human and Animal Drugs	Date Published: 09/17/2010
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62 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
63 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	
64 - - - - Human and Animal Drugs	Date Published: 09/17/2010
Notes:All drug products	

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

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

Date Published : 09/30/2013

Date Published: 09/30/2013

50 - - - - Color Additiv Food/Drug/Cosmetic
Desc:All drug and drug products

Date Published: 09/30/2013

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

Date Published: 09/30/2013

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

Date Published: 09/30/2013

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

Date Published: 09/30/2013

61 - - - - Human and Animal Drugs
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Date Published: 09/30/2013

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

Date Published: 09/30/2013

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

Date Published: 09/30/2013

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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

55 R - - 99 Pharmaceutic Necessities, N.E.C.
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

57 D - - 38 Whole Blood (Human) Heparin (Blood and Blood Derivatives)
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

61 L - - 08 Heparin Sodium (Anti-Coagulant)
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

61 L - - 22 Anti-Coagulant Heparin Sol
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

61 L - - 30 Heparin Calcium (Anti-Coagulant)
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

74 L - - IS Heparin Coating Chemicals,
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

80 N - - ZW Heparin Vascular access flush
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

81 J - - BR Test, Heparin Neutralization
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

81 J - - OX Analyzer, Heparin, Automated
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

81 K - - FF Assay, Heparin
Notes:All heparin products 3/10/2008

Date Published: 09/10/2009

88 I - - AZ Heparin
Notes:All heparin products 3/10/2008

**China Resources Sanjiu Medical and Pharmaceutical Co., Ltd.
No. 1 Guanqing Rd , Guanlan Hi-Tech Park, Longhua District , Shenzhen , Guangdong CHINA**

Date Published : 09/03/2014

Date Published: 09/03/2014

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

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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

Chongqing Imperial Bio Chem Co 5 Yanghesancun , 19-7 Citic Bank Building, Jiangbei Dist. , Jiangbei, Zhongqingshi CHINA	Date Published : 09/10/2009
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 C NO. 2 4th Branch Road Hua'Nan Rd , Changshou , Zhongqing, Zhongqing CHINA	Date Published : 04/19/2016
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 Lummy Pharmaceutical Co. Ltd. Economic And Technological , NO. 2 the 4th Branch Rd, Huaa??Nan Road , Chongqing, Changshou District CHINA	Date Published : 04/19/2016
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 158 Gonglongpo , Yudong , Chongqing, CHINA	Date Published : 09/10/2009
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

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

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

Date Published : 05/10/2012

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 Dagu- , Nan Road, Hexi , Tianjin,China , tianjin, CN-12 CHINA**

Date Published : 09/17/2010

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

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

Date Published : 09/10/2009

Date Published: 09/10/2009

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

Date Published: 09/10/2009

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

**Guangzhou Haishi Biological Technology Co., Ltd.
1/F,2/F, Bldg.1, no.3, Songyuan Rd , New Industrial Zone, No.11 She, Xiamao , Guangdong, Guangzhou CHINA**

Date Published : 03/14/2016

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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

Date Published: 03/14/2016

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

Date Published: 03/14/2016

Date Published: 03/14/2016

Date Published: 03/14/2016

Date Published: 03/14/2016

Date Published: 03/14/2016

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

Hebei Yuxing Bio-Engineering Co Ltd
Xicheng District , Ningjin County , Ningjin, Hebei CHINA

Date Published : 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

Date Published: 07/08/2016

54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
Desc:All Drugs and Drug Products
Notes:Problem(s); (GMP) Good Manufacturing Practices

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

Huzhou Aupower Sanitary Commodity
339 Jingsan Road , Changxing Dist , Huzhou, Zhejiang CHINA

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

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

Date Published: 08/05/2016

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

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

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

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

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

**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

Date Published: 09/10/2009

56 - - - - Antibiotics (Human/Animal)

Notes:8/30/2007

Date Published: 09/10/2009

60 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

61 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

62 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

63 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

64 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

65 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

66 - - - - Human and Animal Drugs

Notes:8/30/2007

Date Published: 09/10/2009

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)

Date Published: 10/18/2011

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

Desc:Heparin Sodium (Anti-Coagulant)

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

Notes:All Drug Products

Date Published: 03/27/2013

53 - - - - Cosmetics

Notes:All Drug Products

Date Published: 03/27/2013

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

Notes:All Drug Products

Date Published: 03/27/2013

60 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

61 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

62 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

63 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

64 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

65 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

66 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 03/27/2013

80 - - - - General Hospital/Personal Use

Notes:All Drug Products

Date Published: 03/27/2013

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

Notes:All Drug Products

Date Published: 04/08/2011

56 - - - - Antibiotics (Human/Animal)

Notes:All Drug Products

Date Published: 04/08/2011

60 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

61 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

62 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

63 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

64 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

65 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

66 - - - - Human and Animal Drugs

Notes:All Drug Products

Date Published: 04/08/2011

Ningbo Unichem Household Products Co Ltd.**NO. 27 Luotuo Jiedao Jiushu Fangnanlu ,****Date Published : 03/05/2013****Zhenhai , Ningbo, Zhejiang CHINA**

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: 03/05/2013
 Date Published: 03/05/2013
 Date Published: 03/05/2013
 Date Published: 03/05/2013
 Date Published: 03/05/2013
 Date Published: 03/05/2013
 Date Published: 03/05/2013
 Date Published: 03/05/2013

Northeast Pharmaceutical Group Co., Ltd.**37 Zhonggong Bei Street , Tiexi District , Shenyang, 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

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

Date Published : 04/03/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 04/03/2013
60 - - - - Human and Animal Drugs	Date Published: 04/03/2013
61 - - - - Human and Animal Drugs	Date Published: 04/03/2013
62 - - - - Human and Animal Drugs	Date Published: 04/03/2013
63 - - - - Human and Animal Drugs	Date Published: 04/03/2013
64 - - - - Human and Animal Drugs	Date Published: 04/03/2013
65 - - - - Human and Animal Drugs	Date Published: 04/03/2013
66 - - - - Human and Animal Drugs	Date Published: 04/03/2013

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

Date Published : 03/28/2014

53 E - - 06 Shampoos (Hair Preparations, Non-coloring) Desc:Dandruff Shampoo Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
53 F - - 04 Hair Shampoos (Coloring) (Hair Coloring Preparations) Desc:Dandruff Shampoo Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
53 J - - 99 Other Personal Cleanliness Products (not Antiperspirant), N.E.C. Desc:Hand Sanitizers Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
53 J - - - - Personal Cleanliness Desc:Antiperspirants Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
53 L - - 03 Face,Body,and Hand (excluding Shaving Preparations) (Skin Care Preparations) Desc:Hand Sanitizers Notes:(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
60 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
61 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
62 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
63 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
64 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
65 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014
66 - - - - Human and Animal Drugs Notes:All Drugs;(GMP) Good Manufacturing Practices	Date Published: 03/28/2014

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.
387 Shangqiulu , Shonghaish, Shonghaish 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 - - 1S 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

**Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.
1317 Jianchuanlu , Minhang District , 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 Biochem & Pharma Co., Ltd.
494 Zhongxing Road , Room A-403 , 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 Notes:All drug products	Date Published: 05/08/2012
61 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 05/08/2012
62 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 05/08/2012
63 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 05/08/2012
64 - - - - Human and Animal Drugs Notes:All drug products	Date Published: 05/08/2012
65 - - - - Human and Animal Drugs	Date Published: 05/08/2012

Date Published: 05/08/2012

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

**Suzhou No. 4 Pharmaceutical Factory
171 Baiyanglu , Suzhou City, Jiangsusheng CHINA**

Date Published : 07/10/2014

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

- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014
- Date Published: 07/10/2014

**Taizhou Kanglin Health Protection Prods Co
No 1 Yaocheng Ave Room 1754 Bldg 1 , Taizhou, CHINA**

Date Published : 01/15/2013

- 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
- 55 - - - - Pharm Necess & Ctnr For Drug/Bio
- 56 - - - - Antibiotics (Human/Animal)
- 60 - - - - Human and Animal Drugs
- 61 - - - - Human and Animal Drugs
- 62 - - - - Human and Animal Drugs
- 63 - - - - Human and Animal Drugs
- 64 - - - - Human and Animal Drugs
- 65 - - - - Human and Animal Drugs
- 66 - - - - Human and Animal Drugs
- 80 L - - KB Pad, Alcohol

- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013

**Taizhou Kanglin Health Protection Products Co Ltd.
8 Dongjinlu , Hailing , Taizhou, Jiangsu CHINA**

Date Published : 01/15/2013

- 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
- 55 - - - - Pharm Necess & Ctnr For Drug/Bio
- 56 - - - - Antibiotics (Human/Animal)
- 60 - - - - Human and Animal Drugs
- 61 - - - - Human and Animal Drugs
- 62 - - - - Human and Animal Drugs
- 63 - - - - Human and Animal Drugs
- 64 - - - - Human and Animal Drugs
- 65 - - - - Human and Animal Drugs
- 66 - - - - Human and Animal Drugs
- 80 L - - KB Pad, Alcohol

- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013

**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)
- 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 L - - KB Pad, Alcohol

- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
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- Date Published: 01/15/2013

**Taizhou Kanglin Health Protection Products Co.,Ltd.
No.1 East 1 Rd. Economical Dev. , Taizhou, Jiangsu, CHINA**

Date Published : 01/15/2013

- 54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
- 55 - - - - Pharm Necess & Ctnr For Drug/Bio
- 56 - - - - Antibiotics (Human/Animal)
- 60 - - - - Human and Animal Drugs
- 61 - - - - Human and Animal Drugs
- 62 - - - - Human and Animal Drugs
- 63 - - - - Human and Animal Drugs
- 64 - - - - Human and Animal Drugs
- 65 - - - - Human and Animal Drugs
- 66 - - - - Human and Animal Drugs
- 80 L - - KB Pad, Alcohol

- Date Published: 01/15/2013
- Date Published: 01/15/2013
- Date Published: 01/15/2013
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- Date Published: 01/15/2013
- Date Published: 01/15/2013

Tianjin Boai NKY International Ltd.**Suites 1808-9 Guohua Building , Dagu-Nan 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

Date Published: 09/17/2010

Notes:All drug products

64 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

65 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

66 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

Tianjin Boai Pharmaceutical Co. Ltd**No.4, Ronghua Road, Xiqing District , Yong Hong Industry Zone, Nan He Town , Tianjin, Tianlushi 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

Date Published: 09/17/2010

Notes:All drug products

64 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

65 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

66 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

Tianjin Boai Pharmaceutical Ltd. co.**6, Rd Ronghua , Town Nanhe, Dist. Xiqing , Tianjin , 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

Date Published: 09/17/2010

Notes:All drug products

64 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

65 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

66 - - - - Human and Animal Drugs

Date Published: 09/17/2010

Notes:All drug products

Tianjin Zhongan Pharmaceutical Co., Ltd.**Xiqing , 188 Fukang Road , Tianjin, Tianjin CHINA****Date Published : 02/11/2016**

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

Date Published: 02/11/2016

Notes:Problem: (GMP) Good Manufacturing Practices

56 - - - - Antibiotics (Human/Animal)

Date Published: 02/11/2016

Notes:Problem: (GMP) Good Manufacturing Practices

60 - - - - Human and Animal Drugs

Date Published: 02/11/2016

Notes:Problem: (GMP) Good Manufacturing Practices

61 - - - - Human and Animal Drugs

Date Published: 02/11/2016

Notes:Problem: (GMP) Good Manufacturing Practices 62 - - - - Human and Animal Drugs	Date Published: 02/11/2016
Notes:Problem: (GMP) Good Manufacturing Practices 63 - - - - Human and Animal Drugs	Date Published: 02/11/2016
Notes:Problem: (GMP) Good Manufacturing Practices 64 - - - - Human and Animal Drugs	Date Published: 02/11/2016
Notes:Problem: (GMP) Good Manufacturing Practices 65 - - - - Human and Animal Drugs	Date Published: 02/11/2016
Notes:Problem: (GMP) Good Manufacturing Practices 66 - - - - Human and Animal Drugs	Date Published: 02/11/2016

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 , Xinxiang, Henan, CHINA****Date Published : 04/06/2016**

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****Date Published : 04/06/2016**

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

**Yunnan Hande Bio-Tech. Co. Ltd.
No. 3 Platform Jinding Tech Zone , Kunming, Yunnan CHINA**

Date Published : 05/20/2016

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

**Zhejiang Casing Animal By-Products Co.,Ltd.
369 Dong Xing Road , Tonglu Economic Developing District , Hangzhou, Zhejiang Province CN-33 CHINA**

Date Published : 10/18/2011

61 L - - 08 Heparin Sodium (Anti-Coagulant) Desc:Heparin Sodium (Anti-coagulant)	Date Published: 10/18/2011
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**Zhejiang Hisoar Pharmaceutical Co. Ltd.
No. 100 Waisha Branch Rd , Jiaojiang , Taizhou City, Zhejiang Province CHINA**

Date Published : 01/20/2016

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 01/20/2016
56 - - - - Antibiotics (Human/Animal) Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 01/20/2016
60 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 01/20/2016
61 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 01/20/2016
62 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 01/20/2016
63 - - - - Human and Animal Drugs Notes:All Drugs and Drug Products;Problem(s): (GMP) Good Manufacturing Practices	Date Published: 01/20/2016

Date Published: 01/20/2016

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

Date Published: 01/20/2016

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

Date Published: 01/20/2016

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

Zhejiang Hisun Pharmaceutical Co., Ltd.**Date Published : 09/09/2015****46 Waisha Road , Jiaojiang District , Taizhou City, Zhejiang CHINA**

Date Published: 09/09/2015

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

Date Published: 02/18/2016

56 H - S 25 Daunorubicin Hydrochloride (Antitumor), Active Pharm Ingrid/Chems for Further Manuf
Desc:Daunorubicin Hydrochloride
Notes:

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

Date Published: 09/09/2015

56 - - - - Antibiotics (Human/Animal)
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[[]02, be excluded from dwpe under this firm listing;

Date Published: 09/09/2015

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

Date Published: 09/09/2015

61 - - - - Human and Animal Drugs
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe:Granisetron 61T[S24;
CDER has recommended Mesna, 61R[[]22, be excluded from dwpe under this firm listing.

Date Published: 09/09/2015

62 - - - - Human and Animal Drugs
Notes:All Drugs; Problem(s): (GMP) Good Manufacturing Practices; These products are excluded from dwpe: Cladribine 62I[S74;
Cyclophosphamide 62I[[]15 finished form and API; Cytarabine 62I[S16;Floxuridine 62V[S06; Fludarabine 62I[S79;Ivermectin
62L[S47

Date Published: 09/09/2015

63 - - - - Human and Animal Drugs
Notes:All Drugs;These products are excluded from dwpe:Adenosine 63E[S18

Date Published: 09/09/2015

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

Date Published: 09/09/2015

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

Date Published: 09/09/2015

66 - - - - Human and Animal Drugs
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**

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Date Published: 11/24/2015

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

Zhejiang Zonebanner Jiuzhou**Date Published : 03/18/2014****Waisha Road 99 Jia , Taizhou, CHINA**

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

Date Published: 03/18/2014

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

DENMARK

Leo Pharma A/S
Industriparken 55 , Ballerup, DENMARK

Date Published : 03/01/2011

Date Published: 03/01/2011

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.

Leo Pharmaceutical Products
A 8 , Copenhagen, DENMARK

Date Published : 03/01/2011

Date Published: 03/01/2011

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.

Leo Pharmaceutical Products
Park Alle 26 , Vejlen, DENMARK

Date Published : 03/01/2011

Date Published: 03/01/2011

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.

Plum A/S
Frederik Plums Vej 2 , Assens, DENMARK

Date Published : 05/13/2015

Date Published: 05/13/2015

65 F - - 06 Water, Purified (Eyewash)
Desc:Plum Emergency Eyewash (Sterile)

FRANCE

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

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 - - - - 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

Compagnie Oris Industrie, S.A.
Centre D'Etudes Nucleaires De Marcoule , BP 171f , Bagnols, FRANCE

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 - - - - 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

Societe Chimique Grevis
Avenue De La Paix , Limay, FRANCE

Date Published : 09/10/2009

Date Published: 09/10/2009

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	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	
61 - - - - Human and Animal Drugs	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	
62 - - - - Human and Animal Drugs	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	
63 - - - - Human and Animal Drugs	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	
64 - - - - Human and Animal Drugs	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	
65 - - - - Human and Animal Drugs	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	
66 - - - - Human and Animal Drugs	Date Published: 09/10/2009
Notes: Sterile bulk pharmaceutical chemicals 8/10/1989	

GERMANY

Biologische Heilmittel Heel Gmbh
P O Box 729 , Ruhrstrasse 14 , Baden-Baden, GERMANY

Date Published : 09/10/2009

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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	Date Published: 09/10/2009
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.	

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	Date Published: 07/08/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)	Date Published: 07/08/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 07/08/2013
56 - - - - Antibiotics (Human/Animal)	Date Published: 07/08/2013
60 - - - - Human and Animal Drugs	Date Published: 07/08/2013
61 - - - - Human and Animal Drugs	Date Published: 07/08/2013
62 - - - - Human and Animal Drugs	Date Published: 07/08/2013
63 - - - - Human and Animal Drugs	Date Published: 07/08/2013
64 - - - - Human and Animal Drugs	Date Published: 07/08/2013
65 - - - - Human and Animal Drugs	Date Published: 07/08/2013
66 - - - - Human and Animal Drugs	Date Published: 07/08/2013

GREECE

CHIA GH LTD.
Ag. Mina 144 , Chios, GREECE

Date Published : 05/06/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/06/2013
56 - - - - Antibiotics (Human/Animal)	Date Published: 05/06/2013
60 - - - - Human and Animal Drugs	Date Published: 05/06/2013
61 - - - - Human and Animal Drugs	Date Published: 05/06/2013
62 - - - - Human and Animal Drugs	Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013

63 - - - - Human and Animal Drugs

64 - - - - Human and Animal Drugs

65 - - - - Human and Animal Drugs

66 - - - - Human and Animal Drugs

GUADELOUPE**Ligne St. Barth SAS****Route De Saline , Lorient , Saint Barthelemy, GUADELOUPE****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

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

HONG KONG**CBSICHEM LIMITED****13Floor, Nan Fung Ind. City , No. 18 Tin Hau Road , TUEN MUN, NEW TERRITORIES HONG KONG****Date Published : 08/31/2013**

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

Date Published: 08/31/2013

35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling

Desc:All drugs and drug products

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

Desc:All drugs and drug products

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

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs

Notes:All drugs and drug products

61 - - - - Human and Animal Drugs

Notes:All drugs and drug products

62 - - - - Human and Animal Drugs

Notes:All drugs and drug products

63 - - - - Human and Animal Drugs

Notes:All drugs and drug products

64 - - - - Human and Animal Drugs

Notes:All drugs and drug products

65 - - - - Human and Animal Drugs

Notes:All drugs and drug products

66 - - - - Human and Animal Drugs

Notes:All drugs and drug products

78 - - - - Gastroenterological & Urological

Desc:All drugs and drug products

88 - - - - Pathology

Desc:All drugs and drug products

Chan Yat Hing Medicine Factory**Flat 3, 9/F, Fuk Keung Industrial Bldg. , 66-68 Tong Mei Road , Mongkok, Kowloon, HONG KONG****Date Published : 12/03/2015**

Date Published: 01/07/2016

53 - - - - Cosmetics

Desc:All drug products declared as Cosmetic Products

Notes:The firm has a history of importing some of the following drug products under product code 53: Arthritis Pain Relieving Cream, Pain Relieving Balm, Wok Lok Pain Relieving Oil, Shuang Long Pain Relieving Oil, and Red Flower Oil, Pain Relieving Herbal Oil, Pain Relieving Chi Len Oil, Pain Relieving Po Tong Oil, and Back Pain Relieving Oil. This is not an inclusive list; therefore it is recommended that any products offered for import under product code 53 be thoroughly reviewed to determine if said products are drug products and thus subject to DWPE under this listing.

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

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

Date Published: 12/03/2015

56 - - - - Antibiotics (Human/Animal)

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

Date Published: 12/03/2015

60 - - - - Human and Animal Drugs

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

Date Published: 12/03/2015

61 - - - - Human and Animal Drugs

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

Date Published: 12/03/2015

62 - - - - Human and Animal Drugs

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

Date Published: 12/03/2015

63 - - - - Human and Animal Drugs

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

Date Published: 12/03/2015

64 - - - - Human and Animal Drugs

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

Date Published: 12/03/2015

65 - - - - Human and Animal Drugs

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

Date Published: 12/03/2015

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.**Unit B, 7F, Phase 1 Leader Industry Ctr. , 188-202 Texaco Rd, Tsuen Wan , Kowloon, HK-NA HONG KONG****Date Published : 03/04/2014**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 03/04/2014
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014

Peking Medicine Manufactory**Unit B, 7/F, Phase 1, Leader Industry , Centre, 188-202 Texaco Road , Tsuen Wan, Kowloon, HONG KONG****Date Published : 03/04/2014**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug Products	Date Published: 03/04/2014
60 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
61 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
62 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 03/04/2014

Seedings**18 Tin Hau Rd. , Room 3, 13/F, Tower 4 , Hong Kong, Hong Kong HONG KONG****Date Published : 08/31/2013**

35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling Notes:All drugs and drug products	Date Published: 08/31/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Notes:All drugs and drug products	Date Published: 08/31/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 08/31/2013
56 - - - - Antibiotics (Human/Animal) Notes:All drugs and drug products	Date Published: 08/31/2013
60 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
61 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
62 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
63 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
64 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
65 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
66 - - - - Human and Animal Drugs Notes:All drugs and drug products	Date Published: 08/31/2013
78 - - - - Gastroenterological & Urological Notes:All drugs and drug products	Date Published: 08/31/2013
88 - - - - Pathology Notes:All drugs and drug products	Date Published: 08/31/2013

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

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

Amsal Chem Pvt. Ltd.**Date Published : 04/11/2013****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

Apotex Pharmachem India Pvt Ltd.**Date Published : 04/01/2014****1a Bommasandra , Plot No ;; 4'th Phase , Bangalore, Karnataka INDIA**

Date Published: 04/01/2014

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

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

56 - - - - Antibiotics (Human/Animal)

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

60 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

61 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

62 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices This product is excluded from DWPE: Riluzole tablets 62J[[[16];

Date Published: 04/01/2014

63 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

64 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

65 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

66 - - - - Human and Animal Drugs

Notes:(GMP) Good Manufacturing Practices

Date Published: 04/01/2014

Apotex Research Private Limited**Date Published : 09/22/2014****#2 Site , Jigani Link Rd; 4'th Phase , Bangalore, Karnataka INDIA**

Date Published: 09/22/2014

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

Notes:Good Manufacturing Practices (GMP);

Date Published: 09/22/2014

56 - - - - Antibiotics (Human/Animal)

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

60 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

61 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

62 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP); These products are excluded from DWPE Riluzole tablets (62J[[[16) and Abacavir tablets (62V[[[17).

Date Published: 09/22/2014

63 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

64 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

65 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

66 - - - - Human and Animal Drugs

Notes:Good Manufacturing Practices (GMP)

Date Published: 09/22/2014

Canton Laboratories Pvt. Ltd.**Date Published : 04/10/2014****110 A & B Gidc Estate , Makarpura Road; M I Estate , 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 ;

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 Limited**Date Published : 04/11/2011****Plot No. 48, Temple Rock Enclave , Tarbund X Road , Secunderabad, INDIA**

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

Fleming Laboratories Ltd.**Survey No 270 (Old no.: 364/1), , Kanukuta Road, , Shivampet Mandal, Medak District, Andhra Pradesh INDIA****Date Published : 04/08/2011**

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 04/08/2011
56 - - - - Antibiotics (Human/Animal)	Date Published: 04/08/2011
60 - - - - Human and Animal Drugs	Date Published: 04/08/2011
61 - - - - Human and Animal Drugs	Date Published: 04/08/2011
62 - - - - Human and Animal Drugs	Date Published: 04/08/2011
63 - - - - Human and Animal Drugs	Date Published: 04/08/2011
64 - - - - Human and Animal Drugs	Date Published: 04/08/2011
65 - - - - Human and Animal Drugs	Date Published: 04/08/2011
66 - - - - Human and Animal Drugs	Date Published: 04/08/2011

Ipca Laboratories LTD**1 Pharma Zone , Pithampur, Madhya Pradesh 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 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 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**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-608, MIDC, Kupwad , Sangli, M.S., 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
T-47 Kagel Hatkanangale Five Star, MIDC , Talandage (Village), Tal: Kagal , Maharashtra State, INDIA

Date Published : 07/10/2013

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.
Plot No. 876, N.H. - 8 , Vill: Hariyala, Tal: Matar , Kheda, Gujarat INDIA

Date Published : 03/12/2014

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
48 - 51/201 Plot No 31 - 35 , Lakhmapur, Maharashtra INDIA

Date Published : 10/14/2015

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All Drug and Drug Products	Date Published: 10/14/2015
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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 : 08/21/2013****Plot No. 113-116 4th Phase KIADB , Bommasandra Industrial Area,Anekal Taluk , Bangalore, INDIA**

50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drugs and drug products	Date Published: 08/21/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drugs and drug products	Date Published: 08/21/2013
60 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
61 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
62 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
63 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
64 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
65 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013
66 - - - - Human and Animal Drugs Notes:Desc -- All drugs and drug products	Date Published: 08/21/2013

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 Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
64 - - - - Human and Animal Drugs Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
65 - - - - Human and Animal Drugs Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014
66 - - - - Human and Animal Drugs Notes:All drugs and drug products (GMP) Good Manufacturing Practices	Date Published: 09/19/2014

Nivedita Chemicals P ITd**Date Published : 11/23/2011****A14 MIDC Andheri East , Mumbai, IN-MH INDIA**

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:Chlorpheniramine maleate	Date Published: 11/23/2011
60 - - - - Human and Animal Drugs Notes:Chlorpheniramine maleate	Date Published: 11/23/2011
61 X - - 08 Chlorpheniramine Maleate (Anti-Histaminic) Desc:Chlorpheniramine maleate	Date Published: 11/23/2011
61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Desc:Chlorpheniramine maleate	Date Published: 11/23/2011
61 X - - 29 Pyrilamine Maleate (Anti-Histaminic) Desc:Pyrilamine maleate Pyrilamine maleate USP	Date Published: 11/23/2011
61 X - - 99 Anti-Histaminic N.E.C. Desc:Pyrilamine maleate Pyrilamine maleate USP	Date Published: 11/23/2011
61 - - - - Human and Animal Drugs Notes:Chlorpheniramine maleate	Date Published: 11/23/2011
62 - - - - Human and Animal Drugs	Date Published: 11/23/2011

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

Nivedita Chemicals Pvt. Ltd.**A-14 M.I.D.C. Andheri (East) , Maharashtra, MS 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 Ppyrilamine Maleate (Anti-Histaminic)
 Desc:Ppyrilamine maleate Ppyrilamine maleate USP
 61 X - - 29 Ppyrilamine Maleate (Anti-Histaminic)
 Desc:Chlorpheniramine maleate
 61 X - - 99 Anti-Histaminic N.E.C.
 Desc:Ppyrilamine maleate Ppyrilamine 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
 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: 12/08/2015

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

Date Published: 12/08/2015

Date Published: 12/08/2015

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

Date Published: 05/05/2015

Date Published: 05/05/2015

Date Published: 05/05/2015

Date Published: 05/05/2015

Date Published: 05/05/2015

Date Published: 05/05/2015

Date Published: 05/05/2015

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

**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

Date Published: 09/11/2015

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

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

Date Published: 09/11/2015

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

60 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

61 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

62 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

63 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

64 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

65 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

66 - - - - Human and Animal Drugs

Date Published: 09/11/2015

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

**RPG Life Sciences Limited
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

Date Published: 06/10/2013

64 - - - - Human and Animal Drugs

Date Published: 06/10/2013

65 - - - - Human and Animal Drugs

Date Published: 06/10/2013

66 - - - - Human and Animal Drugs

Date Published: 06/10/2013

**RPG Life Sciences Limited
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

**Ranbaxy Laboratories Limited
Phase III Industrial Area SAS Nagar , Mohali, Punjab, INDIA**

Date Published : 09/13/2013

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

Date Published: 09/13/2013

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

Date Published: 09/13/2013

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

Sentiss Pharma Pvt. Ltd.**Village Khara Nihla, , Tehsil Nalargarh , District Solan, , Himachal Pradesh INDIA****Date Published : 06/20/2013**

Date Published: 06/20/2013

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

Date Published: 06/20/2013

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

Date Published: 06/20/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 06/20/2013

60 - - - - Human and Animal Drugs

Date Published: 06/20/2013

61 - - - - Human and Animal Drugs

Date Published: 06/20/2013

62 - - - - Human and Animal Drugs

Date Published: 06/20/2013

63 - - - - Human and Animal Drugs

Date Published: 06/20/2013

64 - - - - Human and Animal Drugs

Date Published: 06/20/2013

65 - - - - Human and Animal Drugs

Date Published: 06/20/2013

66 - - - - Human and Animal Drugs

Date Published: 06/20/2013

86 - - - - Ophthalmic

Smruthi Organics Limited**Plot No. A-27, MIDC, Chincholi , Solapur District, Maharashtra, INDIA****Date Published : 06/03/2013**

Date Published: 06/03/2013

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

Date Published: 06/03/2013

60 - - - - Human and Animal Drugs

Date Published: 06/03/2013

61 - - - - Human and Animal Drugs

Date Published: 06/03/2013

62 - - - - Human and Animal Drugs

Date Published: 06/03/2013

63 - - - - Human and Animal Drugs

Date Published: 06/03/2013

64 - - - - Human and Animal Drugs

Date Published: 06/03/2013

65 - - - - Human and Animal Drugs

Date Published: 06/03/2013

66 - - - - Human and Animal Drugs

Sri Krishna Pharmaceuticals Ltd. - Unit II**A-35, IDA, Nacharam , Hyderabad, Andhra Pradesh, INDIA****Date Published : 08/13/2015**

Date Published: 08/13/2015

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

Date Published: 08/13/2015

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

Date Published: 08/13/2015

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

Date Published: 08/13/2015

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

Date Published: 08/13/2015

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

Date Published: 08/13/2015

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

Date Published: 08/13/2015

65 - - - - Human and Animal Drugs
Notes:All Drugs;This product is excluded from dwpe: Sodium Phenylbutyrate granules/65C[[[09

Date Published: 08/13/2015

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

Date Published: 08/13/2015

Srikem Laboratories Pvt. Ltd.**Plot No. 17/24, MIDC Taloja , Navi Mumbai, INDIA****Date Published : 07/06/2016**

Date Published: 07/06/2016

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

Date Published: 07/06/2016

56 - - - - Antibiotics (Human/Animal)

Date Published: 07/06/2016

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

Date Published: 07/06/2016

60 - - - - Human and Animal Drugs

Date Published: 07/06/2016

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

Date Published: 07/06/2016

61 - - - - Human and Animal Drugs

Date Published: 07/06/2016

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

Date Published: 07/06/2016

62 - - - - Human and Animal Drugs

Date Published: 07/06/2016

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

Date Published: 07/06/2016

63 - - - - Human and Animal Drugs

Date Published: 07/06/2016

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

Date Published: 07/06/2016

64 - - - - Human and Animal Drugs

Date Published: 07/06/2016

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

Date Published: 07/06/2016

65 - - - - Human and Animal Drugs

Date Published: 07/06/2016

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

Date Published: 07/06/2016

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.**No. 9, Sub Layout Of Plot 9 , 1st Phase Bommasandra Ind. Area , Bangalore, Karnataka INDIA****Date Published : 01/13/2011**

Date Published: 01/13/2011

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

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

Sun Pharmaceutical Industries (prev. Ranbaxy) 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 Desc:All drugs and drug products	Date Published: 09/13/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal) Desc:All drug and drug products	Date Published: 09/13/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drugs and drug products	Date Published: 09/13/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drugs and drug products	Date Published: 09/13/2013
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

Sun Pharmaceutical Industries (prev. Ranbaxy) Date Published : 09/10/2009
Industrial Area No. 3 , Madhya Pradesh , Dewas, Madhya Pradesh INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
56 - - - - Antibiotics (Human/Animal) 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.	Date Published: 09/10/2009
60 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
61 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
62 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
63 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
64 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
65 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009
66 - - - - Human and Animal Drugs Notes:All finished pharmaceutical products and APIs 9/16/2008 NOTE: This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.	Date Published: 09/10/2009

Sun Pharmaceutical Industries (prev. Ranbaxy) Date Published : 09/10/2009
Village Ganguwala , Tehsil, Paonta Sahib , Simour District, Himachal Pradesh INDIA

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 09/10/2009
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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

Unique Chemicals

Date Published : 06/28/2013

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

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

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

Notes:All drugs and drug products

56 - - - - Antibiotics (Human/Animal)

Date Published: 06/28/2013

Desc:All drugs and drug products

60 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

61 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

62 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

63 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

64 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

65 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

66 - - - - Human and Animal Drugs

Date Published: 06/28/2013

Notes:All drugs and drug products

Vignesh Life Science Pvt Ltd

Date Published : 06/28/2013

202 Sarada Residency , H - 26 , Madhura Nagar Ameerpet , Hyderabad, Tamil Nadu INDIA

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

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

Desc:All drugs and drug products

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

Date Published: 06/28/2013

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

Vignesh Life Sciences Pvt., Ltd.
93 & 94 P Mundargi Industrial Estate , Bellary Karnataka, INDIA

Date Published : 06/28/2013

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

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

Date Published : 11/26/2013

50 - - - - Color Additiv Food/Drug/Cosmetic	Date Published: 11/26/2013
Desc:Drugs and Drug products	
55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 11/26/2013
56 - - - - Antibiotics (Human/Animal)	Date Published: 11/26/2013
Desc:Drugs and Drug products	
60 - - - - Human and Animal Drugs	Date Published: 11/26/2013
61 - - - - Human and Animal Drugs	Date Published: 11/26/2013
62 - - - - Human and Animal Drugs	Date Published: 11/26/2013
Notes:* Notes: These products are excluded from DWPE: Enalapril Maleate (Antihypertensive - part II) (62OCA28, 62OCS28)	
63 - - - - Human and Animal Drugs	Date Published: 11/26/2013
64 - - - - Human and Animal Drugs	Date Published: 11/26/2013
65 - - - - Human and Animal Drugs	Date Published: 11/26/2013
66 - - - - Human and Animal Drugs	Date Published: 11/26/2013

Wockhardt Limited
Plot H-14/2, Biotech Park , M.I.D.C. Area Waluj , Aurangabad, Maharashtra INDIA

Date Published : 05/22/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio	Date Published: 05/22/2013
Notes:All Drugs and drug products;	
56 - - - - Antibiotics (Human/Animal)	Date Published: 05/22/2013
Notes:All Drugs and drug products;	
60 - - - - Human and Animal Drugs	Date Published: 05/22/2013
Notes:All Drugs and drug products;	
61 - - - - Human and Animal Drugs	Date Published: 05/22/2013
Notes:All Drugs and drug products;	
62 - - - - Human and Animal Drugs	Date Published: 05/22/2013
Notes:All Drugs and drug products Except -- Enalapril Maleate (62O[[[28)	
63 - - - - Human and Animal Drugs	Date Published: 05/22/2013
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

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

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

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

Date Published: 08/05/2016

Yag Mag Labs Private Limited**Survey No. 10, Gaddapotharam Village, , Jinnatam Mandel , Medak District, AP, INDIA**

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

Date Published: 09/13/2011

60 L - - 99 Analgesic, N.E.C.

Date Published: 09/13/2011

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

Date Published: 09/13/2011

ITALY**Topchem SRL****Viale Andrea Doria 17 , Milano, MI ITALY**

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

Date Published : 09/10/2009**JAMAICA****P.A. Benjamin Manufacturing Co., Ltd.****95-97 East Street , Kingston, JAMAICA**

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

Date Published: 08/29/2012

60 - - - - Human and Animal Drugs

Date Published: 08/29/2012

61 - - - - Human and Animal Drugs

Date Published: 08/29/2012

62 - - - - Human and Animal Drugs

Date Published: 08/29/2012

63 - - - - Human and Animal Drugs

Date Published: 08/29/2012

64 - - - - Human and Animal Drugs

Date Published: 08/29/2012

65 - - - - Human and Animal Drugs

Date Published: 08/29/2012

66 - - - - Human and Animal Drugs

Date Published: 08/29/2012

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

Date Published: 02/13/2013

Notes:All Drugs Products

60 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

61 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

62 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

63 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

64 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

65 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

66 - - - - Human and Animal Drugs

Date Published: 02/13/2013

Notes:All Drugs Products

Kanebo Cosmetics Inc.

Date Published : 05/06/2013

3-28, Kotobuki-Cho 5-Chome , Odawara-shi Kanagawa, Kanagawa-ken JAPAN

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

Date Published: 05/06/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 05/06/2013

60 - - - - Human and Animal Drugs

Date Published: 05/06/2013

61 - - - - Human and Animal Drugs

Date Published: 05/06/2013

62 - - - - Human and Animal Drugs

Date Published: 05/06/2013

63 - - - - Human and Animal Drugs

Date Published: 05/06/2013

64 - - - - Human and Animal Drugs

Date Published: 05/06/2013

65 - - - - Human and Animal Drugs

Date Published: 05/06/2013

66 - - - - Human and Animal Drugs

Date Published: 05/06/2013

KOREA, REPUBLIC OF (SOUTH)

K J I Industrial Co., Ltd.

Date Published : 09/04/2013

29 Gyeseok-ro, Dong-myeon , Yangsan-si, Gyeongsangnam-do, KOREA, REPUBLIC OF (SOUTH)

53 - - - - Cosmetics

Date Published: 09/04/2013

Desc:All drugs and drug products

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

Date Published: 09/04/2013

Desc:All drugs and drug products

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

Date Published: 09/04/2013

Notes:All drugs and drug products

60 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

61 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

62 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

63 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

64 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

65 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

66 - - - - Human and Animal Drugs

Date Published: 09/04/2013

Notes:All drugs and drug products

80 - - - - General Hospital/Personal Use

Date Published: 09/06/2013

Desc:All Drugs and Drug Products

81 - - - - Hematology

Date Published: 09/04/2013

Desc:All drugs and drug products

89 - - - - Physical Medicine

Date Published: 09/04/2013

Desc:All drugs and drug products

LG 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

Date Published: 05/06/2013

53 - - - - Cosmetics

Date Published: 05/06/2013

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

Date Published: 05/06/2013

56 - - - - Antibiotics (Human/Animal)

Date Published: 05/06/2013

60 - - - - Human and Animal Drugs

Date Published: 05/06/2013

61 - - - - Human and Animal Drugs

Date Published: 05/06/2013

62 - - - - Human and Animal Drugs

Date Published: 05/06/2013

63 - - - - Human and Animal Drugs

Date Published: 05/06/2013

64 - - - - Human and Animal Drugs

Date Published: 05/06/2013

65 - - - - Human and Animal Drugs

Date Published: 05/06/2013

Date Published: 05/06/2013

Date Published: 05/06/2013

66 - - - - Human and Animal Drugs
 80 - - - - General Hospital/Personal Use

MEXICO**Compania Internacional de Comercio, S.A. P.I. de C.V.****Monzon No. 184 , Cerro de la Estrella, Iztapalapa , Mexico City, , Distrito Federal MEXICO****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

Date Published: 05/17/2012

Date Published: 05/17/2012

Date Published: 05/17/2012

Farma Quimia S.A. de C.V.**Av Andre Marie Ampere No 11 , Parque Industrial Cuamatla , Cuautitlan Izcalli, Mex MEXICO****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

Date Published: 02/23/2012

Date Published: 02/23/2012

Prosintesis S.A. de C.V.**Avenida Educacion s/n , Pueblo Santa Maria Mazatlan , Jilotingo, Mexico MEXICO****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****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

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

SINGAPORE

Licht Far East (S) Pte Ltd 2 Woodlands Sector 1 , #05-04 , Singapore, SINGAPORE

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

Date Published: 03/28/2014

Date Published: 03/28/2014

Date Published: 03/28/2014

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

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

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

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

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

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

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

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

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

SOUTH AFRICA

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

Date Published : 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

Date Published: 09/17/2010

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

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

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

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

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

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

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

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

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

SPAIN

Dysers S.A.L. Depositos 12 , Segovia, SPAIN

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

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

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

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

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

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

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

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

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

Jabones Pardo S.A.
Calle Sierra Nevada 1 , Fuenlabrada, Madrid SPAIN

Date Published : 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

Date Published: 10/01/2013

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

TAIWAN

Beanne Chemical Co.
No. 28, Lane 456, Fongihou Road , Shengang District , Taichung City, TAIWAN

Date Published : 09/28/2012

Date Published: 09/28/2012

Date Published: 09/28/2012

Date Published: 09/28/2012

- 50 - - - - Color Additiv Food/Drug/Cosmetic
 Desc:All drug and drug products
- 53 - - - - Cosmetics
 Desc:All drug and drug products
- 56 - - - - Antibiotics (Human/Animal)
 Desc:All drug and drug products

Taiwan Three Mast Pharmaceutical Co., Ltd.
3 Jingzhong Rd. , Tainan City, TAIWAN

Date Published : 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

Date Published: 09/04/2012

- 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

THAILAND

PAN RAJDHEVEE GROUP PUBLIC COMPANY LIMITED
50/234-275 MOO 3, LAT SA WAI, LAM LUK KA , Lam Luk Ka, Pathum Thani THAILAND

Date Published : 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

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

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

Date Published : 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

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

Notes:All Drug and Drug Products
 56 - - - - Antibiotics (Human/Animal)
 Notes:All Drug and Drug Products
 60 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products
 61 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products
 62 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products
 63 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products
 64 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products
 65 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products
 66 - - - - Human and Animal Drugs
 Notes:All Drug and Drug Products

Date Published: 03/10/2015

Date Published: 03/10/2015

Date Published: 03/10/2015

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
Zone Industrielle Kalaa El Kebira , Sousse, Sousse TUNISIA
 65 F - - 06 Water, Purified (Eyewash)
 Desc:Cederroth Emergency Eye Wash

Date Published : 02/03/2015

Date Published: 02/03/2015

TURKEY

Ansa
UNKNOWN , Izmit, TURKEY
 56 - - - - Antibiotics (Human/Animal)

Date Published : 09/10/2009

Date Published: 09/10/2009

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

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

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

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

Date Published: 01/31/2012

UNITED KINGDOM

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

Date Published : 09/10/2009

Date Published: 09/10/2009

Date Published: 09/10/2009

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

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 Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
60 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
61 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
62 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
63 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
64 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
65 - - S -- Human and Animal Drugs, Active Pharm Ingrid/Chems for Further Manuf Notes:All bulk pharmaceuticals 1/26/1996	Date Published: 09/10/2009
66 - - S -- Human and Animal Drugs, Active Pharm Ingrid/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.**Calle 6, Centro Empresarial R.S. , Zona Industrial de La Urbina , 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 Notes:All Drug Products	Date Published: 05/14/2010
63 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
64 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
65 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010
66 - - - - Human and Animal Drugs Notes:All Drug Products	Date Published: 05/14/2010

VIETNAM

Rohto-Mentholatum (Vietnam) Company, Ltd. 16 VSIP Street 5 , Vietnam-Singapore Industrial Park , Thuan An Town, Binh Duong Province VIETNAM	Date Published : 08/26/2013
50 - - - - Color Additiv Food/Drug/Cosmetic Desc:All drug and drug products	Date Published: 08/26/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio Notes:All drug and drug products	Date Published: 08/26/2013
56 - - - - Antibiotics (Human/Animal) Desc:All drug and drug products	Date Published: 08/26/2013
60 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
61 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
62 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
63 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
64 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
65 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013
66 - - - - Human and Animal Drugs Notes:All drug and drug products	Date Published: 08/26/2013

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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)
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