Import Alert 66-40

(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: 04/10/2014
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

Contract Pharmaceutical Services of Australia Pty Ltd
5 Eden Park Drive, North Ryde, NSW AUSTRALIA

61 E - - -- A-Asthmatic
Desc:Aridol Bronchial Challenge Test Kits
63 X - - -- Diag Aid (Drugs)
Desc:Aridol Bronchial Challenge Test Kits

Pharmaxis Ltd
Unit 2, 10 Rodborough Road, Frenchs Forest, NSW AUSTRALIA

61 E - - -- A-Asthmatic
Desc:Aridol Bronchial Challenge Test Kits
63 X - - -- Diag Aid (Drugs)
Desc:Aridol Bronchial Challenge Test Kits

Radpharm Scientific
57 Oatley Court, Belconnen, AUSTRALIA

Notes:Nexavir

BELGIUM

Qualipharm Nv
Rijksweg 9, Bornem, BELGIUM

55 - - -- Pharm Necess & Ctnr For Drug/Bio
Notes:All drug products
60 - - -- Human and Animal Drugs
Notes:All drug products
61 - - -- Human and Animal Drugs
Notes:All drug products
62 - - -- Human and Animal Drugs
Notes:All drug products
63 - - -- Human and Animal Drugs
Notes:All drug products

Date Published : 05/28/2013
Date Published: 05/28/2013
Date Published: 05/28/2013
Date Published: 05/28/2013
Date Published: 05/28/2013
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

### CANADA

**Aleeda Inc**  
7115 Tomken Rd, Mississauga, ON CANADA  

<table>
<thead>
<tr>
<th>Notes: All Drug Products</th>
<th>Date Published: 05/29/2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 - - - - Pharm Necess &amp; Ctnr For Drug/Bio</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>60 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>61 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>62 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>63 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>64 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>65 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
<tr>
<td>66 - - - - Human and Animal Drugs</td>
<td>Date Published: 05/29/2012</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Notes: All Drug Products</th>
<th>Date Published: 04/10/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 R - - 55 Sodium Chloride (Pharmaceutical Necessity - Tonicity Agent) Desc: 0.9% Sodium Chloride Injection USP</td>
<td>Date Published: 04/10/2014</td>
</tr>
<tr>
<td>65 R - - 12 Potassic Saline (Injection) (Replenisher) Desc: 0.9% Sodium Chloride Injection USP</td>
<td>Date Published: 04/10/2014</td>
</tr>
</tbody>
</table>

**International Laboratories (Canada) Ltd.**  
63 Skyline Crescent Ne, Calgary, Alberta CANADA  

<table>
<thead>
<tr>
<th>Notes: All Drug Products</th>
<th>Date Published: 03/14/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>55 - - - - Pharm Necess &amp; Ctnr For Drug/Bio</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>60 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>61 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>62 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>63 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>64 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>65 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>66 - - - - Human and Animal Drugs</td>
<td>Date Published: 03/14/2014</td>
</tr>
<tr>
<td>Company</td>
<td>Date Published</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Pax-All Manufacturing Inc</td>
<td>02/23/2012</td>
</tr>
<tr>
<td>5000 Howard Business Parkway, Windsor, Ontario CANADA</td>
<td></td>
</tr>
<tr>
<td>55 - - - - Pharm Necess &amp; Ctnr For Drug/Bio</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>60 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>61 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>62 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>63 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>64 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>65 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>66 - - - - Human and Animal Drugs</td>
<td>Date Published: 02/23/2012</td>
</tr>
<tr>
<td>Notes: All Drug Products</td>
<td>Date Published: 02/23/2012</td>
</tr>
</tbody>
</table>

**CHINA**

<table>
<thead>
<tr>
<th>Company</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOAI NEW KAIYUAN PHARMACY CO., LTD.</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>No.9 ZhongShan Road, Boai City, Jiaosuo, CN-41 CHINA</td>
<td></td>
</tr>
<tr>
<td>55 - - - - Pharm Necess &amp; Ctnr For Drug/Bio</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>56 - - - - Antibiotics (Human/Animal)</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>60 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>61 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>62 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>63 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>64 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>65 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>66 - - - - Human and Animal Drugs</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOAI NKY PHARMACEUTICALS LTD.</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>Suites 1808-9 Guohua Building, 857 Dagu- , Nan Road, Hexi, Tianjin, China, tianjin, CN-12 CHINA</td>
<td></td>
</tr>
<tr>
<td>55 - - - - Pharm Necess &amp; Ctnr For Drug/Bio</td>
<td>Date Published: 09/17/2010</td>
</tr>
<tr>
<td>Notes: All drug products</td>
<td>Date Published: 09/17/2010</td>
</tr>
</tbody>
</table>
Changshu Huagang Pharmaceuticals Co., Ltd
Yuxiang, Yetang Town, Changshu City, , Jiangsu Province, China , Changshu, CN-32 CHINA

Date Published : 09/30/2013

Color Additiv Food/Drug/Cosmetic
Date Published: 09/30/2013

Pharm Necess & Ctnr For Drug/Bio
Date Published: 09/30/2013

Antibiotics (Human/Animal)
Date Published: 09/30/2013

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

Changzhou SPL Company, Ltd
3 Changhong West Rd., , Hutang Township, Wujin City , Changzhou, Jiangsu Province CHINA

Date Published : 09/10/2009

Crude Heparin (Pharmaceutic Necessity)
Date Published: 09/10/2009

Pharmaceutic Necessities, N.E.C.
Date Published: 09/10/2009

Whole Blood (Human) Heparin (Blood and Blood Derivatives)
Date Published: 09/10/2009

Heparin Sodium (Anti-Coagulant)
Date Published: 09/10/2009

Notes: All drug and drug products

Notes: All drug and drug products

Yuxiang, Yetang Town, Changshu City, , Jiangsu Province, China , Changshu, CN-32 CHINA

Notes: All heparin products 3/10/2008

Notes: All heparin products 3/10/2008

Notes: All heparin products 3/10/2008

Notes: All heparin products 3/10/2008

Notes: All heparin products 3/10/2008

Notes: All heparin products 3/10/2008

Notes: All heparin products 3/10/2008
Chongqing Imperial Bio Chem Co
5 Yanghe Sancun, 19-7 Citic Bank Building, Jiangbei Dist., Chongqing, CHINA

55 - - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All API 3/16/2009
Date Published: 09/10/2009

56 - - - - - Antibiotics (Human/Animal)
Notes: All API 3/16/2009
Date Published: 09/10/2009

60 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

61 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

62 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

63 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

64 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

65 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

66 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009

Chongqing Paiquiang Agribyproduct Co., Ltd
158 Gonglongpo, Yudong, Chongqing, CHINA

55 - - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All API 3/16/2009
Date Published: 09/10/2009

56 - - - - - Antibiotics (Human/Animal)
Notes: All API 3/16/2009
Date Published: 09/10/2009

60 - - - - - Human and Animal Drugs
Notes: All API 3/16/2009
Date Published: 09/10/2009
Fercy Personal Care Products Co., Ltd
An’Wen Industrial Zone Pan County, Jinhua, Zhejiang CHINA

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

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
Guangdong Pharmaceutical Factory #1
91 Fangcun Dadao, Guangzhou, CHINA
Date Published: 09/10/2009
61 G - - A-Bacterial Pt. II (Not Antibiotic)
Notes: Active Pharmaceutical Ingredients 12/12/1997
Date Published: 09/10/2009
61 H - - A-Bacterial Pt. III (Not Antibiotic)
Notes: Active Pharmaceutical Ingredients 12/12/1997
Date Published: 09/10/2009

Jiangsu Province Jianerkang Medical Dressing Co.
Zhixi Town, Jintan City, Jiangsu CHINA
Date Published: 04/27/2012
55 - - Pharm Necess & Ctnr For Drug/Bio
Notes: All Drug Products
Date Published: 04/27/2012
56 - - Antibiotics (Human/Animal)
Notes: All Drug Products
Date Published: 04/27/2012
60 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012
61 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012
62 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012
63 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012
64 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012
65 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012
66 - - Human and Animal Drugs
Notes: All Drug Products
Date Published: 04/27/2012

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

55 R - - 75 Crude Heparin (Pharmaceutic Necessity)
Desc: Crude Heparin (Pharmaceutical Necessity)

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

Date Published: 10/18/2011

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

50 - - - Color Additiv Food/Drug/Cosmetic
Notes: All Drug Products

53 - - - Cosmetics
Notes: All Drug Products

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

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

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

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

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

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

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

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

80 - - - General Hospital/Personal Use
Notes: All Drug Products

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
Ningbo Unichem Household Products Co Ltd.
Luotuo Industrial Zone, No. 27 Jiushu Fang Nan Road, Ningbo, Zhenhai CHINA

Notes: All Drug Products

Date Published: 03/05/2013

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

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

Date Published: 09/10/2009
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 Biochemical And Pharmaceutical Co Ltd
Room A403, No. 494 Zhongxing Road, Shanghai, CHINA

Date Published : 09/10/2009

Date Published: 09/10/2009

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

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

57 D - - 36 Whole Blood (Human) Heparin (Blood and Blood Derivatives)
Notes: All heparin products 1/21/2009

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

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

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

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

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

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

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

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

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

Shanghai Huhui Daily Use Chemical Products Co., Ltd.
No 8 Ludalu, Liuzao Town, Pudong District New Area, Shanghai, CHINA

Date Published : 04/03/2013

Date Published: 04/03/2013

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

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

Date Published : 03/28/2014

Date Published: 03/28/2014

53 E - - 06 Shampoos (Hair Preparations, Non-coloring)
Desc: Dandruff Shampoo
Notes: (GMP) Good Manufacturing Practices
Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.

Shangqui Road, Shanghai, CHINA

Date Published: 09/10/2009
Notes: All Heparin Products 1/21/2009

81 J - BR Test, Heparin Neutralization   Date Published: 09/10/2009
Notes: All Heparin Products 1/21/2009

81 J - OX Analyzer, Heparin, Automated   Date Published: 09/10/2009
Notes: All Heparin Products 1/21/2009

81 K - FF Assay, Heparin   Date Published: 09/10/2009
Notes: All Heparin Products 1/21/2009

88 I - AZ Heparin   Date Published: 09/10/2009
Notes: All Heparin Products 1/21/2009

Shanghai No. 1 Biochemical & Pharmaceutical Co., Ltd.   Date Published: 09/10/2009
1317 Jianchuan Road, Minhang District, Shanghai, CHINA

55 - - Pharm Necess & Ctnr For Drug/Bio   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

56 - - Antibiotics (Human/Animal)   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

60 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

61 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

62 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

63 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

64 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

65 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

66 - - Human and Animal Drugs   Date Published: 09/10/2009
Notes: All API’s 1/21/2009 (original) 4/14/2009 (updated) Note: Other Shanghai No. 1 locations remain subject to DWPE for Heparin products only.

Sichuan Pharmaceutical Co., Ltd.   Date Published: 05/08/2012
189 Hua Long Road, Pengzhou, Sichuan Province, CHINA

55 - - Pharm Necess & Ctnr For Drug/Bio   Date Published: 05/08/2012
Notes: All drug products

56 - - Antibiotics (Human/Animal)   Date Published: 05/08/2012
Notes: All drug products

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.

Notes: All drug products

Notes: All drug products

Notes: All drug products

Notes: All drug products

Notes: All drug products

Notes: All drug products
Taizhou Kanglin Health Products Co., Ltd.
The West of Qiliqiao, Economic Development Zone, Taizhou, Jiangsu Province CHINA

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

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

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

Taizhou Kanglin Health Protection Products Co Ltd.
8 Dongui Street, Taizhou Economic Zone, 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  

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

Tianjin Boai NKY International Ltd.  
Suites 1808-9 Guohua Building, Dagu-Nan Road, Hexi District, Tianjin, CN-12 CHINA  
55 - - - -- Pharm Necess & Ctnr For Drug/Bio  

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

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

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

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

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

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

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

Notes: All drug products  

Date Published : 09/17/2010
<table>
<thead>
<tr>
<th>Company Name</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tianjin Boai Pharmaceutical Co. Ltd</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>No.4, Ronghua Road, Xiqing District, Yong Hong Industry Zone, Nan He Town, Tianjin, CN-12 CHINA</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>Tianjin Boai Pharmaceutical Ltd. co.</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>6, Rd Ronghua, Town Nanhe, Dist. Xiqing, Tianjin, Tianjin, CN-12 CHINA</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>Zhejiang Casing Animal By-Products Co., Ltd.</td>
<td>10/18/2011</td>
</tr>
</tbody>
</table>
369 Dong Xing Road, Tonglu Economic Developing District, Hangzhou, Zhejiang Province CN-33 CHINA

Date Published: 10/18/2011

Heparin Sodium (Anti-Coagulant)

Desc:Heparin Sodium (Anti-coagulant)

Zhejiang Jiuzhou Pharmaceutical Co., Ltd.

No. 99 Waisha Road, Taizhou, Zhejiang Prov., Zhejiang 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
Date Published: 03/18/2014

Zhejiang Zonebanne

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
Date Published: 03/18/2014
DENMARK

**Leo Pharma A/S**
**Industrieparken 55, Ballerup, DENMARK**
61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.
61 L - - 99 Anti-Coagulant, N.E.C.
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

**Leo Pharmaceutical Products**
**Park Alle 26, Vejen, DENMARK**
61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.
61 L - - 99 Anti-Coagulant, N.E.C.
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

**Leo Pharmaceutical Products**
**A 8, Copenhagen, DENMARK**
61 L - - 35 Tinzaparin Sodium (Anti-Coagulant)
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.
61 L - - 99 Anti-Coagulant, N.E.C.
Desc:Tinzaparin Sodium (Innohep); Anti-coagulent; n.e.c.

FRANCE

**Compagnie Oris Industrie Lpiib**
**B.P. #2 91 Gif-Sur-Yvette, Saclay, FRANCE**
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**
55 - - --- Pharm Necess & Ctnr For Drug/Bio

Date Published: 03/01/2011

Date Published: 03/01/2011

Date Published: 03/01/2011

Date Published: 03/01/2011

Date Published: 03/01/2011

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
Societe Chimique Grevis

Avenue De La Paix, Limay, FRANCE

Date Published: 09/10/2009

Bavarian Red Cross - Augsburg

Westheimer Strasse 80, Augsburg, GERMANY

Date Published: 09/10/2009
Bavarian Red Cross - Bayreuth

Dr. Franz-Strasse 3, Bayreuth, GERMANY

57 - - - - Bio & Licensed In-Vivo & In-Vitro Diag
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

66 U - - - - Nat Body Part (Invivo Only)
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

Date Published: 09/10/2009

Bavarian Red Cross - Munich

Herzog-Heinrich Strasse 4, Munich, GERMANY

57 - - - - Bio & Licensed In-Vivo & In-Vitro Diag
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

66 U - - - - Nat Body Part (Invivo Only)
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

Date Published: 09/10/2009

Bavarian Red Cross - Nurnberg

Prof. Ernst Nathan Str. 1, Nurnberg, GERMANY

57 - - - - Bio & Licensed In-Vivo & In-Vitro Diag
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

66 U - - - - Nat Body Part (Invivo Only)
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

Date Published: 09/10/2009

Bavarian Red Cross - Regensburg

Hoher Kreuz Weg 7, Regensburg, GERMANY

57 - - - - Bio & Licensed In-Vivo & In-Vitro Diag
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

66 U - - - - Nat Body Part (Invivo Only)
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

Date Published: 09/10/2009

Bavarian Red Cross - Wurzburg

Klinikstrasse 5, Wurzburg, GERMANY

57 - - - - Bio & Licensed In-Vivo & In-Vitro Diag
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

66 U - - - - Nat Body Part (Invivo Only)
Desc: All Products (including Whole Blood; Red Blood Cells and Whole Blood CPDA-1; and Recovered Plasma). Bavarian Red Cross
Operations have multiple facilities operating under license # 1002) 12/29/1998
Notes: Notes

Date Published: 09/10/2009
Heel Gmbh, Biologische Heilmittel
Ruhstr, 14, Baden, GERMANY

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, and Bahnhofstrasse 2-4, Hoya, Niedersachsen GERMANY

50 - - - - Color Additiv Food/Drug/Cosmetic
   Date Published : 07/08/2013
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
   Date Published : 07/08/2013
55 - - - - Pharm Necess & Ctnr For Drug/Bio
   Date Published : 07/08/2013
56 - - - - Antibiotics (Human/Animal)
   Date Published : 07/08/2013
60 - - - - Human and Animal Drugs
   Date Published : 07/08/2013
61 - - - - Human and Animal Drugs
   Date Published : 07/08/2013
62 - - - - Human and Animal Drugs
   Date Published : 07/08/2013
63 - - - - Human and Animal Drugs
   Date Published : 07/08/2013
CHIA GI LTD.
Ag. Minas 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
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

GUADELOUPE

Ligne St. Barth SAS
Route De Saline, Lorient, Saint Barthelemy, GUADELOUPE
Date Published: 07/08/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Date Published: 07/08/2013
60 - - - - Human and Animal Drugs
Date Published: 07/08/2013
61 - - - - Human and Animal Drugs
Date Published: 07/08/2013
62 - - - - Human and Animal Drugs
Date Published: 07/08/2013
63 - - - - Human and Animal Drugs
Date Published: 07/08/2013
64 - - - - Human and Animal Drugs
Date Published: 07/08/2013
65 - - - - Human and Animal Drugs
Date Published: 07/08/2013
66 - - - - Human and Animal Drugs
Date Published: 07/08/2013

HONG KONG

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

35 - - - - Gelatin/Rennet/Pudding Mix/Pie Filling
Date Published: 08/31/2013
Desc: All drugs and drug products
54 - - - - Vit/Min/Prot/Unconv Diet (Human/Animal)
Date Published: 08/31/2013
Desc: All drugs and drug products
55 - - - - Pharm Necess & Ctnr For Drug/Bio
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
Notes: All drugs and drug products

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
Desc: All drugs and drug products
Date Published: 08/31/2013

88 - - - -- Pathology
Desc: All drugs and drug products
Date Published: 08/31/2013

Luen Yick Pharmaceutical Co. Ltd.  
Unit B, 7F, Phase 1 Leader Industry Ctr. , 188-202 Texaco Rd, Tsuen Wan, Kowloon, HK-NA HONG KONG

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

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
Seedings
18 Tin Hau Rd. , Room 3, 13/F, Tower 4 , Hong Kong, Hong Kong HONG KONG

Date Published : 08/31/2013

INDIA

Amsal Chem Pvt. Ltd.
A-1/401-402-403, GIDC, Ankleshwar, Gujarat, INDIA

Date Published : 04/11/2013
<table>
<thead>
<tr>
<th>Plot No.: 1A, Bommasandra, Industrial Area, 4th Phase, Bangalore, INDIA</th>
<th>Date Published: 04/01/2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apotex Pharmachem India Pvt. Ltd.</td>
<td></td>
</tr>
<tr>
<td><strong>Notes:</strong> All Drugs/All Antibiotics; This product is excluded from DWPE: Riluzole tablets 62J][][16; (GMP) Good Manufacturing Practices</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Unit 6, Survey No. 329/39 &amp; 329/47, Chitkul Village, Patancheru Mandal, Hyderabad, Andhra Pradesh INDIA</th>
<th>Date Published: 02/07/2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aurobindo Pharma Limited, Unit VI</td>
<td></td>
</tr>
<tr>
<td><strong>Notes:</strong> All Drugs/All Antibiotics; This product is excluded from DWPE: Riluzole tablets 62J][][16; (GMP) Good Manufacturing Practices</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>60 - - P</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>60 - - S</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>60 - - Y</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>61 - - K</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>61 - - O</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>61 - - P</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>61 - - S</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>61 - - Y</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>61 - - Z</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>62 - - K</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>62 - - O</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>62 - - P</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>62 - - S</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>62 - - Y</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>62 - - Z</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>63 - - K</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>63 - - O</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>63 - - P</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>63 - - S</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>63 - - Y</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>63 - - Z</td>
<td>Human and Animal Drugs</td>
</tr>
<tr>
<td>64 - - K</td>
<td>Gas, Diluent</td>
</tr>
<tr>
<td>64 - - O</td>
<td>Human and Animal Drugs</td>
</tr>
</tbody>
</table>
Import Alert 66-40

http://www.accessdata.fda.gov/cms_ia/importalert_189.html
Global Calcium Pvt
Box 3411, Bangalore, INDIA

Date Published: 08/06/2013
66 - - - - Human and Animal Drugs
Notes: All drugs and drug products

Global Calcium Pvt Ltd
711 Karomangala 111 Block, Bangalore, INDIA
50 - - - - Color Additiv Food/Drug/Cosmetic
Notes: All drugs and drug products
54 - - - - Vit/Min/Prot/Unconv Diet (Human/Animal)
Notes: All drugs and drug products
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All drugs and drug products
56 - - - - Antibiotics (Human/Animal)
Notes: All drugs and drug products
60 - - - - Human and Animal Drugs
Notes: All drugs and drug products
61 - - - - Human and Animal Drugs
Notes: All drugs and drug products
62 - - - - Human and Animal Drugs
Notes: All drugs and drug products
63 - - - - Human and Animal Drugs
Notes: All drugs and drug products
64 - - - - Human and Animal Drugs
Notes: All drugs and drug products
65 - - - - Human and Animal Drugs
Notes: All drugs and drug products
66 - - - - Human and Animal Drugs
Notes: All drugs and drug products

Global Calcium Pvt Ltd
No 1 2 Nd Floor 17th Main, Bangalore, INDIA
50 - - - - Color Additiv Food/Drug/Cosmetic
Notes: All drugs and drug products
54 - - - - Vit/Min/Prot/Unconv Diet (Human/Animal)
Notes: All drugs and drug products
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All drugs and drug products
56 - - - - Antibiotics (Human/Animal)
Notes: All drugs and drug products
60 - - - - Human and Animal Drugs
Notes: All drugs and drug products
61 - - - - Human and Animal Drugs
Notes: All drugs and drug products
62 - - - - Human and Animal Drugs
Notes: All drugs and drug products
63 - - - - Human and Animal Drugs
Notes: All drugs and drug products
64 - - - - Human and Animal Drugs
Notes: All drugs and drug products
65 - - - - Human and Animal Drugs
Notes: All drugs and drug products
66 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Global Calcium Pvt. Limited
125/126 Sipcot Industrial Complex, Hosur, Tamil Nadu INDIA

Notes: All drugs and drug products

Kamud Drugs Pvt. Ltd.
N-608, MIDC, Kupwad, Sangli, M.S., INDIA

Notes: All drugs and drug products

Import Alert 66-40
Konduskar Laboratories Pvt Ltd
T-47 Kagel Hatkanangale Five Star, MIDC, Talandage (Village), Tal: Kagal, , Maharashtra State, INDIA

Marck Biosciences Ltd.
Plot No. 876, N.H. - 8, Vill: Hariyala, Tal: Matar, Kheda, Gujarat INDIA
Micro Labs Limited  
Plot No. 113-116 4th Phase KIADB, Bommasandra Industrial Area, Anekal Taluk, Bangalore, INDIA

Date Published: 08/21/2013

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

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

Date Published: 11/23/2011

55 - - - -- Pharm Necess & Ctnr For Drug/Bio  
Notes: Chlorpheniramine maleate  
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
Nivedita Chemicals Pvt. Ltd.
A-14 M.I.D.C. Andheri (East), Maharashtra, MS INDIA

Notes: Chlorpheniramine maleate
Desc: Chlorpheniramine maleate

Pyrilamine Maleate (Anti-Histaminic)
Desc: Pyrilamine maleate Pyrilamine maleate USP

Anti-Histaminic N.E.C.
Desc: Pyrilamine maleate Pyrilamine maleate USP

RPG Life Sciences Limited
3102/A G.I.D.C. Estate, 393002, Ankleshwar, Gujarat INDIA

Notes: Chlorpheniramine maleate
Desc: Chlorpheniramine maleate
RPG Life Sciences Limited
25, M.I.D.C. Land, Thane-Belapur Road, Thane, Maharashtra INDIA

Date Published : 06/10/2013

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

Date Published : 09/13/2013
Ranbaxy Laboratories Ltd.- Sirmour

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

**Village & Post Office Ganguwala , Tehsil, Paonta Sahib , Simour District, Himachal Pradesh INDIA**

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

Notes: All finished pharmaceutical products and APIs 9/16/2008

**NOTE:** This firm is the sole source of Ganciclovir API. Districts should contact DIOP if entries of Ganciclovir API or finished dosage forms are offered for import.

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.

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.

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.

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.

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.

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.

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.

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.

---

Ranbaxy Laboratories, Ltd.

**Date Published : 09/13/2013**

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

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

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
Ranbaxy Laboratories, Ltd.
Industrial Area No. 3, Madhya Pradesh, Dewas, MP INDIA

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.

Sentiss Pharma (frmly: Promed Exports)
Village Khera Nihla, Tehsil Nalargarh, District Solan, Himachal Pradesh INDIA

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.
<table>
<thead>
<tr>
<th>Company Name</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smruthi Organics Limited</td>
<td>06/03/2013</td>
</tr>
<tr>
<td>Stericon Pharma Pvt. Ltd.</td>
<td>01/13/2011</td>
</tr>
<tr>
<td>Sun Pharmaceutical Industries Limited - Karkhadi</td>
<td>03/12/2014</td>
</tr>
</tbody>
</table>
### Desc: All Human Drug Products

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

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

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

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

---

### Unique Chemicals

**Plot P-10, Shiv Mahape Gansoli , Thane Belapur Road, Maharashtra State , Navi Mumbai, INDIA**  
Date Published: 06/28/2013

**50 - - - - Color Additiv Food/Drug/Cosmetic**  
Date Published: 06/28/2013

**55 - - - - Pharm Necess & Ctnr For Drug/Bio**  
Date Published: 06/28/2013

**56 - - - - Antibiotics (Human/Animal)**  
Date Published: 06/28/2013

**60 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

**61 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

**62 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

**63 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

**64 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

**65 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

**66 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013

---

### Vignesh Life Science Pvt Ltd

**202 Sarada Residency , H - 26 , Madhura Nagar Ameerpet , Hyderabad, Tamil Nadu INDIA**  
Date Published: 06/28/2013

**50 - - - - Color Additiv Food/Drug/Cosmetic**  
Date Published: 06/28/2013

**54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)**  
Date Published: 06/28/2013

**55 - - - - Pharm Necess & Ctnr For Drug/Bio**  
Date Published: 06/28/2013

**56 - - - - Antibiotics (Human/Animal)**  
Date Published: 06/28/2013

**60 - - - - Human and Animal Drugs**  
Date Published: 06/28/2013
Vignesh Life Sciences Pvt., Ltd.
93 & 94 P Mundargi Industrial Estate, Bellary Karnataka, INDIA

Vintac Limited
54/1, Boodhihal Village, Nelamangala, Taluk, Bangalore Rural, Karnataka INDIA
Wintac Limited
163 Reservoir Str, Bangalore, INDIA

Date Published: 03/27/2012

55 - - - - Pharm Necess & Ctrr 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

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

Date Published: 11/26/2013

50 - - - - Color Additiv Food/Drug/Cosmetic
Desc: Drugs and Drug products
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)
55 - - - - Pharm Necess & Ctrr For Drug/Bio
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)
56 - - - - Antibiotics (Human/Animal)
Desc: Drugs and Drug products
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)
60 - - - - Human and Animal Drugs
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)
61 - - - - Human and Animal Drugs
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)
62 - - - - Human and Animal Drugs
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)
63 - - - - Human and Animal Drugs
Notes:* Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex
sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)

Notes: These products are excluded from DWPE: Bethanechol Chloride (Cholinergic) (63NCA03, 63NCS03) Ceftriaxone (cephalosporin antibiotic) (56CCC70, 56CCS70) Enalapril Maleate (Antihypertensive? partII) (62OCA28, 62OCS28) Divalproex sodium (anticonvulsant/antiseizure) (61MCC35, 61MCS35) Venlafaxine Hydrochloride (antidepressant) (61NCB80, 61NCS80)

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)

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

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

ITALY

Topchem SRL

Date Published : 09/10/2009

http://www.accessdata.fda.gov/cms_ia/importalert_189.html
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

JAMAICA

P.A. Benjamin Manufacturing Co., Ltd.
95-97 East Street, Kingston, JAMAICA

55 - - - -- Pharm Necess & Ctnr For Drug/Bio
Notes: All bulk drugs
Date Published: 08/29/2012

60 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

61 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

62 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

63 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

64 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

65 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

66 - - - -- Human and Animal Drugs
Date Published: 08/29/2012

JAPAN

Asada Milling Co., Ltd.
253 Obata Kanra-machi, Kanra-gun, Gunma-ken JAPAN

55 - - - -- Pharm Necess & Ctnr For Drug/Bio
Notes: All Drugs Products
Date Published: 02/13/2013

60 - - - -- Human and Animal Drugs
Notes: All Drugs Products
Date Published: 02/13/2013

61 - - - -- Human and Animal Drugs
Notes: All Drugs Products
Date Published: 02/13/2013

62 - - - -- Human and Animal Drugs
Notes: All Drugs Products
Date Published: 02/13/2013

63 - - - -- Human and Animal Drugs
Notes: All Drugs Products
Date Published: 02/13/2013
Kanebo Cosmetics Inc.
3-28, Kotobuki-Cho 5-Chome , Odawara-shi Kanagawa, Kanagawa-ken JAPAN

Date Published : 05/06/2013

K J I Industrial Co., Ltd.
29 Gyeoseok-ro, Dong-myeon , Yangsan-si, Gyeongsangnam-do, KOREA, REPUBLIC OF (SOUTH)

Date Published : 09/04/2013
Desc: All drugs and drug products

89 - - - - Physical Medicine
Desc: All drugs and drug products

**LG Life Sciences**

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

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

80 - - - - General Hospital/Personal Use
Date Published: 05/06/2013

**ST Pharm Co., Ltd.**

1 No. 802, Sihwa Industrial Complex, Jeongwang-dong, Siheung-si, Gyeonggi-do, KOREA, REPUBLIC OF (SOUTH)

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Date Published: 10/24/2013

Desc: All drugs and drug products

56 - - - - Antibiotics (Human/Animal)
Date Published: 10/24/2013

60 - - - - Human and Animal Drugs
Date Published: 10/24/2013

61 - - - - Human and Animal Drugs
Date Published: 10/24/2013

62 - - - - Human and Animal Drugs
Date Published: 10/24/2013

63 - - - - Human and Animal Drugs
Date Published: 10/24/2013

64 - - - - Human and Animal Drugs
Date Published: 10/24/2013

65 - - - - Human and Animal Drugs
Date Published: 10/24/2013

66 - - - - Human and Animal Drugs
Date Published: 10/24/2013

MEXICO

**Compania Internacional de Comercio, S.A. de C.V.**

Calle Monzon No. 184, Col.Cerro de la Estrella, Mexico, D.F., MEXICO

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Date Published: 05/17/2012

56 - - - - Antibiotics (Human/Animal)
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

Nobilus Ent
UL Metalowa 6a, Kutno, POLAND

Date Published: 03/05/2012

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

Nobilus Ent
Swarzewska 45, Warszawa, POLAND
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All Drug Products
56 - - - - Antibiotics (Human/Animal)
Notes: All Drug Products
60 - - - - Human and Animal Drugs
Notes: All Drug Products
61 - - - - Human and Animal Drugs
Notes: All Drug Products
62 - - - - Human and Animal Drugs
Notes: All Drug Products
63 - - - - Human and Animal Drugs
Notes: All Drug Products
64 - - - - Human and Animal Drugs
Notes: All Drug Products
65 - - - - Human and Animal Drugs
Notes: All Drug Products
66 - - - - Human and Animal Drugs
Notes: All Drug Products

Date Published: 03/05/2012

SERBIA

Hemofarm a.d.
Beogradski put bb, Vrsac, SERBIA
55 - - - - Pharm Necess & Ctnr For Drug/Bio
60 - - - - Human and Animal Drugs
61 - - - - Human and Animal Drugs
62 - - - - Human and Animal Drugs
63 - - - - Human and Animal Drugs
64 - - - - Human and Animal Drugs
65 - - - - Human and Animal Drugs
66 - - - - Human and Animal Drugs

Date Published: 04/26/2012

SINGAPORE

Licht Far East (S) Pte Ltd
2 Woodlands Sector 1, #05-04, Singapore, SINGAPORE
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All Drugs; Problem: (GMP) Good Manufacturing Practices
56 - - - - Antibiotics (Human/Animal)

Date Published: 03/28/2014
### SOUTH AFRICA

**Clover Production**  
200 Constantia Drive, Weltevreden Park, Johannesburg, ZA-GT SOUTH AFRICA  
Date Published: 09/17/2010

<table>
<thead>
<tr>
<th>Notes</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Antibiotics; Problem(s): (GMP) Good Manufacturing Practices</td>
<td>03/28/2014</td>
</tr>
<tr>
<td>All Drugs; Problem: (GMP) Good Manufacturing Practices</td>
<td>03/28/2014</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notes</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sterile drug products</td>
<td>09/17/2010</td>
</tr>
<tr>
<td>Antibiotics (Human/Animal)</td>
<td>09/17/2010</td>
</tr>
</tbody>
</table>

### SPAIN

**Dysers S.A.L.**  
Depositos 12, Segovia, SPAIN  
Date Published: 09/10/2009

<table>
<thead>
<tr>
<th>Notes</th>
<th>Date Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>All sterile drug products</td>
<td>09/10/2009</td>
</tr>
<tr>
<td>Antibiotics (Human/Animal)</td>
<td>09/10/2009</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Notes</th>
<th>Date Published</th>
</tr>
</thead>
</table>
60 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

61 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

62 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

63 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

64 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

65 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

66 - - - - Human and Animal Drugs
Notes: Non-sterile bulk drug products 5/1/1992
Date Published: 09/10/2009

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

Date Published: 10/01/2013

53 - - - - Cosmetics
Desc: All drugs and drug products
Date Published: 10/01/2013

55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All drugs and drug products
Date Published: 10/01/2013

56 - - - - Antibiotics (Human/Animal)
Desc: All drugs and drug products
Date Published: 10/01/2013

60 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

61 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

62 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

63 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

64 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

65 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

66 - - - - Human and Animal Drugs
Notes: All drugs and drug products
Date Published: 10/01/2013

TAIWAN

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

Date Published: 09/28/2012

50 - - - - Color Additiv Food/Drug/Cosmetic
Desc: All drug and drug products
Date Published: 09/28/2012

53 - - - - Cosmetics
Desc: All drug and drug products
Date Published: 09/28/2012
Taiwan Three Mast Pharmaceutical Co., Ltd.

NO. 1-3, Hisn Lo Road, An Ping Ind Area, Tainan, TW-TNN TAIWAN

Date Published: 09/04/2012

Desc: All drug and drug products

Ansa

UNKNOWN, Izmit, TURKEY

Date Published: 09/10/2009

Mustafa Nevzat Ilac Sanayii, A.S.

Cobancesme Mahallesi, Sanayi Caddesi, No. 13, Yenibosna Plant, Yenibosna, Istanbul TURKEY

Date Published: 04/16/2013

Desc: All drug and drug products

UNITED ARAB EMIRATES

Julphar Gulf Pharmaceutical Industries

Airport Road, Digdaga, Ras Al-Khaimah, UNITED ARAB EMIRATES

Date Published: 01/31/2012

Desc: All drug and drug products
UNITED KINGDOM

A Nelson & Co., Ltd.
5-9 Endeavour Way, London, UNITED KINGDOM

Date Published: 06/26/2012

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

Date Published: 09/10/2009

Hampshire Chemicals, Ltd.
Seal Sands Road, Middlesborough, Cleveland UNITED KINGDOM

Date Published: 09/10/2009
Import Alert 66-40

http://www.accessdata.fda.gov/cms_ia/importalert_189.html

Notes: All bulk pharmaceuticals 1/26/1996

VENEZUELA

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

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

Laboratorios L.O. Oftalmi, C.A.
Calle 6, Centro Empresarial R.S. , Zona Industrial de La Urbina , Caracas, VENEZUELA
55 - - - --- Pharm Necess & Ctnr For Drug/Bio
Notes:All Drug Products
56 - - - --- Antibiotics (Human/Animal)
Notes:All Drug Products
60 - - - --- Human and Animal Drugs
Notes:All Drug Products
61 - - - --- Human and Animal Drugs
Notes:All Drug Products
62 - - - --- Human and Animal Drugs
Notes:All Drug Products
63 - - - --- Human and Animal Drugs
Notes:All Drug Products
64 - - - --- Human and Animal Drugs
Notes:All Drug Products
65 - - - --- Human and Animal Drugs
Notes:All Drug Products
66 - - - --- Human and Animal Drugs
Notes:All Drug Products

Date Published : 05/14/2010

VIETNAM

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

Date Published : 08/26/2013