

INDIA

IMPORT ALERT 66-40 and Association with Warning Letters Regarding These Sites

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

In this post I consider the active import alerts in the “66-40” category currently posted on the FDA website for firms located in India and the frequency with which warning letters are associated with the import alerts. The tabulated data does not identify import alerts that may be have put in place and removed within this time period. Addresses are often difficult to unambiguously align, but I’ve made every attempt to do so. Where **warning letters** have been issued, a link(s) are provided.

FROM THE FDA WEBSITE DESCRIBING IMPORT ALERT 66-40: *“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 re-inspection or submission of appropriate documentation to the responsible FDA Center.”

CONCLUSION:

- Currently 41 sites in India are under import alert for failure to comply with GMPs (Table 3).
- For these 41 sites, twenty-one of them, just under half do NOT have associated warning letters. ***Thus, being placed under import alert is no guarantee that a warning letter will be issued regarding the site nor is receiving a warning letter a guarantee of an import alert*** (Table 1).
- Among the active import alerts in this category, four have been issued to a single company, one firm has 3 sites under import alert, nine (9) firms have two sites under import alert and sixteen (16) have a single site under import alert. The firm with four sites is Sun Pharmaceuticals and this includes sites that Sun acquire in their purchase of Ranbaxy Pharmaceuticals (Table 2).
- In three instances, EU reports of GMP non-compliance were issued based on inspections in a similar timeframe. They are identified in Table 3 and summary reports may be found [HERE](#).

TABLE 1: Import Alerts per Calendar Year

Year	NUMBER of Alerts	Import Alerts With Associated Warning Letters	Import Alerts Without Associated Warning Letters
2009	2	2	0
2010	0	0	0
2011	6	2	4
2012	0	0	0
2013	14	5	9
2014	8	7	1
2015	11	4	7
2016	0	0	0
TOTAL to 3/26/2016	41	20	21

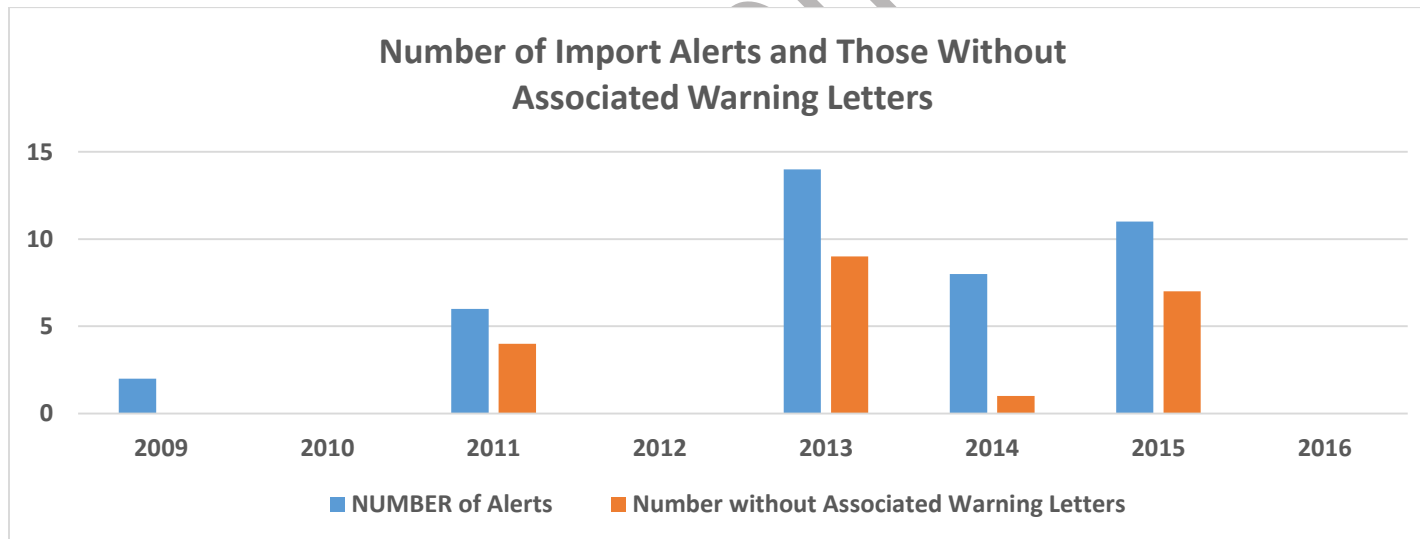
Figure 1. Import Alerts by Year and Those Without Associated Warning Letters

TABLE 2: Active Import Alerts (66-40) per Company Site in India, 2009 – 2016 to date

COMPANY	NUMBER of SITES
Sun Pharmaceuticals (includes sites that were previously Ranbaxy sites)	4
Ipca Laboratories	3
Wockhardt, RPG Life Sciences, Nivedita Chemicals, Flemming Laboratories, Vignesh Life Sciences, Apotex, Pan Drugs, Micro Labs, Aarti Drugs Limited	2 sites for each firm (9 companies, 18 total alerts)
Stericon, Yag Mag Labs, Amsal Chem Pvt Ltd, Smruthi Organics, Sentiss Pharma, Unique Chemicals, Kamud Drugs, Konduskar, Aadvighnesh Chem, Canton Laboratories, Marck Biosciences, Emcure Pharmaceuticals, Sri Krishna Pharmaceuticals, Akorn India, Polydrug Laboratories, Magafine Pharma	1 site for each firm (16 total)

Table 3: Listing of firms/sites in India currently under Import alert 66-40, by Date of Issue

Links are provided to associated warning letter linked to the FDA website

COMPANY	SITE	DATE	OTHER
Sun Pharmaceutical (previously Ranbaxy)	Village Ganguwala, Tehsil, Paonta Sahib, Simour District, Himachal Pradesh INDIA	9/10/2009	Warning Letter June 15, 2006 Warning Letter Sept 16, 2008
Sun Pharmaceutical (previously Ranbaxy)	Industrial Area No. 3, Madhya Pradesh, Dewas, Madhya Pradesh INDIA	9/10/2009	Warning Letter Sept 16, 2008
Stericon Pharma Pvt. Ltd.	No. 9, Sub Layout Of Plot 9, 1st Phase Bommasandra Ind. Area, Bangalore, Karnataka, INDIA	1/13/2011	Warning Letter, August 23, 2010

Fleming Laboratories Ltd.	Survey 270, Navabpet Village, Medak, Andhra Pradesh INDIA	4/8/2011	No warning letter posted This site was the subject of a EU GMP report of non-compliance by the French authorities based on an inspection of October 11, 2013.
Fleming Laboratories Limited	Plot No. 48, Temple Rock Enclave, Tarbund X Road, Secunderabad, INDIA	4/11/2011	No warning letter posted
Yag Mag Labs Private Limited	Survey No. 10, Gaddapotharam Village, Jinnatam Mandel, Medak District, AP, INDIA	9/13/2011	Warning Letter, Sept 12, 2011
Nivedita Chemicals P ITd	A14 MIDC Andheri East, Mumbai, IN-MH INDIA	11/23/2011	No warning letter posted
Nivedita Chemicals Pvt. Ltd.	A-14 M.I.D.C. Andheri (East), Maharashtra, MS INDIA	11/23/2011	No warning letter posted
Amsal Chem Pvt. Ltd.	A-1/401-402-403, GIDC, Ankleshwar, Gujarat, INDIA	4/11/2013	No warning letter posted
Wockhardt Limited	Plot H-14/2, Biotech Park, M.I.D.C. Area Waluj, Aurangabad, Maharashtra INDIA	5/22/2013	Warning Letter, July 18, 2013
Smruthi Organics Limited	Plot No. A-27, MIDC, Chincholi, Solapur District, Maharashtra, INDIA	6/3/2013	Warning Letter, March 6, 2014 This site was the subject of an EU GMP non-compliance report based on an inspection by authorities of the Netherlands, conducted on Oct 16, 2013.
RPG Life Sciences Limited	25, M.I.D.C. Land, Thane-Belapur Road, Thane, Maharashtra INDIA	6/10/2013	Warning Letter, May 28, 2013
RPG Life Sciences Limited	3102/A G.I.D.C. Estate, 393002, Ankleshwar, Gujarat INDIA	6/11/2013	Warning Letter, May 28, 2013

Sentiss Pharma Pvt. Ltd.	Village Khera Nihla, Tehsil Nalargarh, District Solan, Himachal Pradesh INDIA	6/20/2013	No warning letter posted
Unique Chemicals	Plot P-10, Shiv Mahape Gansoli, Thane Belapur Road, Maharashtra State, Rabale, Maharashtra INDIA	6/28/2013	No warning letter posted
Vignesh Life Science Pvt Ltd	202 Sarada Residency, H - 26, Madhura Nagar Ameerpet, Hyderabad, Tamil Nadu INDIA	6/28/2013	No warning letter posted
Vignesh Life Sciences Pvt., Ltd.	93 & 94 P Mundargi Industrial Estate, Bellary Karnataka, INDIA	6/28/2013	No warning letter posted
Kamud Drugs Pvt. Ltd.	N-608, MIDC, Kupwad, Sangli, M.S., INDIA	7/10/2013	No warning letter posted
Konduskar Laboratories Pvt Ltd	T-47 Kagel Hatkanangale Five Star, MIDC, Talandage (Village), Tal: Kagal, Maharashtra State, INDIA	7/10/2013	No warning letter posted
Micro Labs Limited	Plot No. 113-116 4th Phase KIADB, Bommasandra Industrial Area, Anekal Taluk, Bangalore, INDIA	8/21/2013	No warning Letter posted
Sun Pharmaceutical Industries (prev. Ranbaxy)	SEZ Unit 1, Plot No. A-41, Industrial Area Phase VIII-A, SAS Nagar, Mohali, Punjab INDIA <u>This site and data are listed twice on the FDA site but are listed here only once.</u>	9/13/2013	No warning letter posted
Wockhardt Limited	L-1, MIDC Area, Jalgaon Road 43, Chikalthana, Aurangabad, Maharashtra INDIA	11/26/2013	Warning Letter, November 25, 2013
Marck Biosciences Ltd.	Plot No. 876, N.H. - 8, Vill: Hariyala, Tal: Matar, Kheda, Gujarat INDIA	3/12/2014	Warning Letter, July 8, 2014

Sun Pharmaceutical Industries Limited - Karkhadi	Plot No. 817/A, Village - Karkhadi, Taluka - Padra District, Vadodara, Gujarat, INDIA	3/12/2014	Warning Letter, May 7, 2014
Ipca Laboratories LTd	1 Pharma Zone, Pithampur, Madhya Pradesh INDIA	3/25/2014	Warning Letter, Jan 29, 2016
Apotex Pharmachem India Pvt Ltd.	Plot No.: 1A, Bommasandra, Industrial Area, 4th Phase, Bangalore, INDIA	4/1/2014	Warning Letter, June 16, 2014
Canton Laboratories Pvt. Ltd.	110 A & B Gidc Estate, Makarpura Road; M I Estate, Vadodara, Gujarat INDIA	4/10/2014	Warning Letter February 27, 2014
Aadivighnesh Chem PVT. LTD.	A/7 Badrinath Apartment, Simpoli Road, Borivali (West), Mumbai, Maharashtra INDIA	5/5/2014	No warning letter posted
Micro Labs Limited	S - 155 Plot No, Verna Industrial Estate, Vasco Da Gama, Goa INDIA	9/19/2014	Warning Letter, January 9, 2015
Apotex Research Private Limited	Plot 1/2, Site #2 Bommasandra Ind. Area, 4th Phase, Jigani Link Rd., Jigani Hobli, Bangalore, Karnataka State INDIA	9/22/2014	Warning Letter January 30, 2015
Ipca Laboratories Limited	Village Sejavta, Ratlam, Madhya Pradesh INDIA	1/22/2015	Warning Letter, Jan 29, 2016
Aarti Drugs Limited	Plot No. E-22, M.I.D.C., Tarapur, Palghar, Maharashtra INDIA	3/23/2015	Only Warning letter is a previous one dated July 30, 2013
Aarti Drugs Limited	G-60 Boisar MIDC Tarapur, Tal. Palghar, District Thane, Tarapur, Maharashtra INDIA	3/23/2015	Only Warning letter is a previous one dated July 30, 2013
Ipca Laboratories Ltd	1 Pharma Zone, Pithampur, Madhya Pradesh INDIA	3/24/2015	Warning Letter, Jan 29, 2016
Ipca Laboratories Ltd	Plot No. 65 and 99, Danudyog, Ind. Estate, Piparia, Silvasa (D and NH), INDIA	3/24/2015	Warning Letter, Jan 29, 2016

Pan Drugs Ltd.	167-168, GIDC Nandesari Ind. Estate, Nandesari, Vadodara, Gujarat INDIA	5/5/2015	Warning Letter, September 2, 2015
Emcure Pharmaceuticals Limited	Plot No. P-1 & P-2, IT-BT Park Phase II, MIDC, Hinjwadi, Hinjwadi, Pune, Maharashtra INDIA	7/13/2015	Warning letter March 3, 2016,
Sri Krishna Pharmaceuticals Ltd. - Unit II	A-35, IDA, Nacharam, Hyderabad, Andhra Pradesh, INDIA	8/13/2015	No warning letter posted An EU Summary Report of Non-compliance was issued based on an inspection of December 4, 2014 conducted by Italian authorities.
Akorn India PVT	Khasra 5/1, 5/2, 5/3 Village, Nihalgarh Tehsil, Paonta Sahib, Simour, Himachal Pradesh INDIA	8/21/2015	No warning letter posted
Polydrug Laboratories Pvt. Ltd.	Plot N37, Ambernath Industrial Area, Anand Nagar MIDC, Mumbai, Maharashtra INDIA	9/11/2015	No warning letter posted
Megafine Pharma (P) Limited	48 - 51/201 Plot No 31 - 35, Lakhamapur, Maharashtra INDIA	10/14/2015	No warning letter posted
Pan Drugs Limited	192 G I D C Makarpura Industrial Estate, M I Estate, Vadodara, Gujarat INDIA	12/08/2015	No warning letter posted

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