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पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

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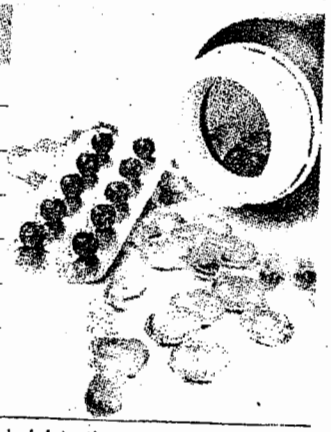
USFDA to restaff as reviews hit

Inspection track record

FY	All foreign countries	India	China
2007	333	64	19
2008	324	64	36
2009	424	59	52
2010	440	72	48
2011	558	98	89
2012	624	141	61
2013	637	111	78
2014*	598	90	88



* (till Aug 4) Source: US Food and Drug Administration
*USFDA fiscal year is from Oct 1 to Sept 30

Pallavi Ail
Mumbai, Aug 8

THE number of inspections by the US Food and Drug Administration (USFDA) in India has come down in the last one year, but the development does not denote that the record of Indian drug manufacturers vis-a-vis compliance with US regulatory standards has improved. Rather, the fewer inspections during the period is due to the fewer staff at the regulator's India office.

The USFDA follows the October-September fiscal year. In FY13 it conducted 111 inspections, which is down to 90 till August 4 of FY14. In FY12 it carried out 141 inspections (see table).

Of 90 inspections done till August 4, there were 70 or so instances where Form 483 — the first observation report on conclusion of an inspection documenting the issues identified — was issued, against 101 such forms issued in FY13 and 107 in FY12.

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Regulatory

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USFDA...

The USFDA conducted 598 investigations in foreign countries excluding China, where it conducted 88 inspections till August 4. There are 517 registered firms in China and 519 in India, which makes India the host to the highest number of USFDA-approved facilities outside the US.

USFDA has a staff strength of 14 in India, of which only six are for probing medical products, which is quite low considering that the agency had an approval to raise the medical products investigators to 19 from 12 in March 2013. Again, of the six, only three are permanent. "USFDA has six medical products investigators in India — three are permanent, and three are long-term detailees (staff who are in the country typically for 90-120 days)," spokesperson Christopher Kelly said.

Altaf Lal, who was the director of the agency in India, resigned from his post in May 2014. He had held the post since June 2013. Carl Sciacchitano, senior science adviser in USFDA's Office of International Programmes, is serving as acting director, India. His appointment began on June 1. Kelly said USFDA expects to name a permanent director in the coming months, and is in the fi-

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nal stages of hiring additional investigators. "Once fully staffed, this will increase our presence to 19 permanent American staff based in-country, including 10 dedicated to medical products," Kelly added.

In comparison, China has 13 staff posted in three locations: Beijing, Shanghai and Guangzhou. This includes eight US civil servants and five Chinese staff. The regulator has plans to expand the China office and when fully staffed, it will include 27 US civil servants and seven Chinese staff, according to Kelly. The China employees include policy and technical experts in Beijing, and inspectors in Shanghai and Guangzhou, who inspect firms that export USFDA-regulated goods to the US.

"Since the opening of its China office in 2008, USFDA has dramatically increased the number of Chinese firms it inspects each year," Kelly said.

India is an important market for the US regulator as it accounted for 40% of US generic drug imports in FY13, which makes it the largest supplier of generic drugs to the country by volume, according to a May 7 India Ratings & Research report. "India Ratings believes that Indian pharmaceuticals manufacturers will face increased USFDA inspections. This is considering the US' increasing dependence on Indian pharmaceuticals manufacturers and the bad press earned by Indian pharmaceuticals on account of the recent spate of import alerts," the report said.

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