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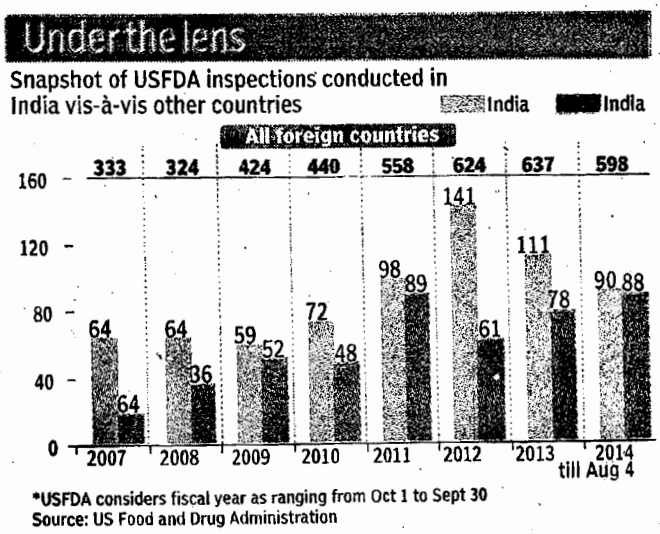
# Natco, Orchid get a strong dose of US FDA medicine




**Pallavi Ail**
Mumbai, Sept 17

NATCO Pharma and Orchid Chemicals and Pharmaceuticals have received an adverse observation report, commonly known as Form 483, after inspections conducted in their manufacturing units earlier this year by the US Food and Drug Administration, according to documents reviewed by *FE*.

Natco, which was in news for battling Teva Pharmaceutical Industries over the patent of the latter's multiple sclerosis drug Copaxone, was issued the Form 483 dated May 23 after a five-day inspection of its finished dosage facility located in Mahabubnagar district in Telangana.

The regulator has made six observations, all of which pertain to quality control standards.

"There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality and purity they purport or are represented to possess," USFDA investigator Luis Dasta wrote.

The report, addressed to BR Reddy, director (operations), pharma division, Natco, adds that the quality control unit "lacks responsibility to approve or reject procedures or specifications" that impact quality and purity of drugs.

**Continued on Page 2**

Regulatory

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## Natco...

The Mahabubnagar facility manufactures around 1,500 million tablets and capsules and 45 million tonnes of pellets annually, and employs 600 people, according to Natco's website. Natco did not respond to queries seeking comment.

The USFDA inspected Orchid's manufacturing unit located in Waluj in Maharashtra in late April 2014. The regulator issued seven observations in its report where they raised issues with the company's quality system.

The inspection report, signed by USFDA inspectors Kham Phommschanh and Paul Bonneau, says "test procedures are not scientifically sound and appropriate to ensure that raw materials, intermediates and active pharmaceutical ingredients (APIs) conform to established standards of quality and purity".

The report, dated April 25 and addressed to Orchid's executive vice-president of manufacturing, PN Deshpande, gives an example of a technician whose process of disinfecting the hand "may possibly resulted in false negative findings".

"Equipment cleaning/-sanitation study does not address microbiological and endotoxin contamination for those processes where there is a need to reduce total microbiological count or endotoxins in the API, or other processes where such contamination could be of concern (example: non-sterile APIs used to manufacture sterile products)," the investigators wrote.

US based injectable drugmaker Hospira bought Orchid's generic injectable pharmaceuticals business in December 2009 for $400 million and its API and research and development facilities in August 2012 for $218 million, according to Bloomberg.

"The Form 483 observations have been responded to appropriately. The Aurangabad plant is part of the Business Transfer Agreement (BTA) with Hospira and has been transferred to them. The BTA was entered into in August 2012 and the transaction was completed in early July 2014, for which the cash consideration was also received," an Orchid spokesperson said in an emailed statement.

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 ratings agency India Ratings and Research, in a report dated May 7, 2014. India has 588 registered facilities compared with 611 for China till August 2, according to a USFDA spokesperson.

The regulator has conducted 90 inspections in India since October 2013.