PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Telegraph, Kolkata
Tuesday 2nd February 2016, Page: 10
Width: 16.83 cms, Height: 10.07 cms, a4, Ref: pmin.2016-02-03.24.25

Drug firms face flak again

OUR SPECIAL CORRESPONDENT

Mumbai, Feb. 1: Domestic pharmaceutical companies continue to face flak from the US Food and Drug Administration (FDA). The regulator has issued a warning letter to IPCA Laboratories on operations at three manufacturing facilties and has made observations on a facility of Hyderabad-based Aurobindo Pharma following an inspection.

Last year, the FDA had inspected IPCA's manufacturing units at Ratlam, SEZ Indore and Piparia (Silvassa) after which these facilities received certain inspection observations in Form 483, following which an import alert was issued on these units.

KNOW YOUR RULES

Form 483: An FDA form where violations observed by inspectors are listed in a prescribed format. Charges are preliminary and companies have the right to reply

Warning letter: Official message from FDA about violations. Respondent expected to take corrective action. Warning letter does not imply enforcement by FDA.

Import alert: Consignments will be detained without inspection if alert is issued.

FDA enforcement: In the nature of drug recalls, seizures

"We wish to inform you that the FDA has now issued a warning letter to these manufacturing units," IPCA Laboratories said in a filing to the bourses today.

The company is fully committed to resolve the issue at the earliest, it added. The mid-sized company, however, did not provide the details of the warning letter.

The announcement led to IPCA shares sliding over 16 per cent in intra-day trades on the bourses. However, the counter managed to recover a large part of the losses and end with losses of 2.02 per cent, or Rs 13.50, at Rs 655.35.

The regulator inspected two of Aurobindo Pharma's facilities and has issued observations about one of them.

"The said facilities underwent pre-approval inspection by the FDA and there was no Form 483 issued to unit III. With regard to unit VII, there were certain observations," it said.

According to the FDA, a Form 483 is issued to a company at the conclusion of an inspection if an investigator observes any conditions which may amount to violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

Sun Pharma

Sun Pharma has launched the generic version of Novartis anti-cancer drug Gleevec in the US market. Being a first-to-file product, it will enjoy 180 days of marketing exclusivity.

-

Regulatory.