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Ranbaxy arm under US FDA scanner

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New Delhi The US Food and Drug Administration has rapped Ranbaxy's US-based subsidiary, Ohm Labs Inc, for manufacturing an old 'unapproved drug'—opium tincture—in a New York manufacturing facility.
Opium tincture is a rarely used prescription drug for treating diarrhea. It also has analgesic properties.

Ranbaxy has been asked to get in touch with the FDA arm dealing with unapproved drugs to sort out the issue. In such cases, the FDA usually goes for a risk-based assessment first, and then could either demand voluntary compliance by issuing a warning letter or initiate seizure. It could also take more stringent action if the matter is found to be serious enough.

Experts that FE spoke with said the charge against Ranbaxy does not appear serious enough for FDA to take any stern action at this juncture.
While the statement put out by Ranbaxy in December acknowledged the charges that US FDA made on account of good manufacturing practices in a warning letter to its facility located in Gloversville, New York, it made no mention about the problem related to opium tincture manufacturing.

The Ranbaxy spokesperson refused to comment on the issue.
In recent months, Ranbaxy has been under fire in the US for the alleged GMP (good manufacturing facility) violation regarding a few other drugs also. The company was alleged to have flouted GMP at the Ohm facility for Ranitidine HCL Solution. Earlier the FDA had banned products from Ranbaxy's India-based facilities in Dewas and Paonta Sahib, even as the company got a nod for the plants from other regulators, including that of Japan and Australia. The company is currently awaiting an US FDA inspection at its Dewas plant and has sought the US regulator's clearance to start selling drugs from a new facility at Mohali.

Ranbaxy had divested the disputed product to Illinois-based Marathon Pharmaceuticals in 2008. In a letter dated October 6, 2008 Bill Winter, vice-president, trade sales, Ranbaxy said "Any open orders (regarding opium tincture) have been cancelled in our system… You will be receiving further communication from Marathon outlining the specifics". Following this, Marathon officially launched the drug on October 27, 2008 and said in a statement, "Marathon purchased opium tincture and two other products from Ranbaxy Pharmaceuticals for commercialization and development in the United States". The CEO of Marathon Robert S Altman said, "We are pleased to announce that opium tincture is now available in the US healthcare system under the Marathon label".

This is one of those antiquated drugs, which has been selling in the US market before Federal Food, Drug & Cosmetic Act of 1938 came into force. So the drug like thousands of other drugs which were selling before this Act was enforced has never been required to undergo the strict FDA drug review and approval process. However since 2006, FDA has issued a guidance and is actively working at either phasing out these drugs from the market or bringing them under the regulatory framework by gathering evidence on the drugs to ensure their safety and efficacy.