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## News & Events

### FDA NEWS RELEASE

#### FOR IMMEDIATE RELEASE

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## FDA Issues Warning Letters to Ranbaxy Laboratories Ltd., and an Import Alert for Drugs from Two Ranbaxy Plants in India

### *Actions affect over 30 different generic drugs; cites serious manufacturing deficiencies*

The Food and Drug Administration (FDA) today issued two Warning Letters to Ranbaxy Laboratories Ltd., of the Republic of India, and an Import Alert for generic drugs produced by Ranbaxy's Dewas and Paonta Sahib plants in India.

The Warning Letters identify the agency's concerns about deviations from U.S. current Good Manufacturing Practice (cGMP) requirements at Ranbaxy's manufacturing facilities in Dewas and Paonta Sahib (including the Batamandi unit), in India. Because of the extent and nature of the violations, FDA today issued an Import Alert, under which U.S. officials may detain at the U.S. border, any active pharmaceutical ingredients (API) (the primary therapeutic component of a finished drug product) and both sterile and non-sterile finished drug products manufactured at these Ranbaxy facilities and offered for import into the United States.

The problems at these two Ranbaxy plants relate to deficiencies in the company's drug manufacturing process. These actions are proactive measures that the FDA is taking in order to assure that all drugs that reach the American public are manufactured according to cGMP requirements. While this action does not involve removing products from the market, FDA has no evidence to date that Ranbaxy has shipped defective products. We will continue to monitor the situation.

Today's announcement does not impact products from Ranbaxy's other plants which are not affected by today's actions. FDA has inspected those facilities and, to date, they have met U.S. cGMP requirements for drug manufacturing.

The FDA recommends that consumers continue taking their medications manufactured by Ranbaxy and not disrupt their drug therapy, which could jeopardize their health. Patients who are concerned about their medications should discuss their concerns with their health care professional.

Earlier today, the FDA informed Ranbaxy that until it resolves the deficiencies at each of these two facilities and the plants come into compliance with U.S. cGMP requirements, FDA's drug compliance office will recommend denial of approval of any New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs) that list the Paonta Sahib or Dewas plants respectively as the manufacturer of APIs or finished drug products

Ranbaxy is one of the largest foreign suppliers of generic drugs to the United States. The company

makes a number of drug products.

The FDA Import Alert covers more than 30 different generic drug products (**Drug List**) produced in multiple dosage forms and dosage amounts ( i.e., 25 mg, 50 mg, and 100 mg) at these two locations. FDA has evaluated whether these actions would create any potential drug shortages in the United States, and has determined that other suppliers can meet market demand, with one exception. Because Ranbaxy is the sole supplier to the U.S. of one drug product, Ganciclovir oral capsules (an antiviral drug), to avoid creating a shortage of the drug, FDA generally will not detain shipments of this product, and plans to arrange for additional oversight and controls until the company resolves these manufacturing issues.

"With this action we are sending a clear signal that drug products intended for use by American consumers must meet our standards of safety and quality," said Janet Woodcock, M.D., director, FDA's Center for Drug Evaluation and Research (CDER). "The FDA has notified other agencies and health care professionals to make them aware of today's actions so that they can take appropriate action and advise patients as needed." The Warning Letters issued today document the results of FDA investigations at these two sites.

One Warning Letter addressed problems at Ranbaxy's Dewas facility found during an inspection conducted by FDA in early 2008. During that inspection, FDA investigators documented significant cGMP deviations in the manufacture of sterile and non-sterile finished products and violations with respect to the manufacture and control of APIs. Specific areas of concern included the following aspects of the firm's quality control program:

- The facility's beta-lactam containment program (measures taken to control cross-contamination), which appeared inadequate to prevent the potential for cross-contamination of pharmaceuticals;
- Inadequate batch production and control records;
- Inadequate failure investigations; (A failure investigation is done to address any manufacturing control or product rejection to determine the root cause and prevent recurrence); and,
- Inadequate aseptic (sterile) processing operations.

The second Warning Letter addressed the Paonta Sahib facility following an inspection at its Batamandi unit, also in early 2008. This inspection documented various cGMP deficiencies, including the following:

- The lack of assurance responsible individuals were present to determine the firm was taking necessary steps under cGMP;
- Inaccurate written records of the cleaning and use of major equipment;
- Incomplete batch production and control records; and,
- Inadequate procedures for the review and approval of production and control records for drug products.

Following the two inspections, FDA provided Ranbaxy with a separate list of inspectional findings for each of the facilities. In mid-April and May, Ranbaxy responded in writing to these findings in lengthy submissions to FDA. The agency then evaluated its findings, Ranbaxy's responses, and the firm's overall inspectional history, an evaluation that required substantial time due to the complex scientific and technical nature of both the identified deficiencies, particularly at the Dewas site, and the firm's responses. Ultimately, FDA concluded that the firm's responses were not adequate and that the Warning Letters were the appropriate regulatory response.

"Today's actions are clearly warranted by the serious violations established by FDA's investigations at these two sites," said Deborah M. Autor, director, CDER's Office of Compliance, FDA. "Until the company addresses these deficiencies, APIs and finished drug products from these plants will remain on the Import Alert, and we will not approve any Abbreviated New Drug Applications or New Drug Applications that list either of the two facilities as the manufacturer of APIs or finished drug products."

This represents the second time in less than three years FDA has issued a Warning Letter to

Ranbaxy. In 2006, FDA cited Ranbaxy for violations of U.S. cGMP at its Paonta Sahib facility.

The FDA will continue to work with Ranbaxy's Dewas and Paonta Sahib plants to resolve these issues.

Consumers and health-care professionals can report adverse events to FDA's MedWatch program at 1-800-FDA-1088; by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787; or online, at the following Internet address: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm).

Links to the Warning Letters:

[http://www.fda.gov/foi/warning\\_letters/s6922c.htm](http://www.fda.gov/foi/warning_letters/s6922c.htm)

[http://www.fda.gov/foi/warning\\_letters/s6923c.htm](http://www.fda.gov/foi/warning_letters/s6923c.htm)

Link to Consumer Questions and Answers:

<http://www.fda.gov/cder/drug/infopage/ranbaxy/qa.htm>

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