Drugs

Questions and Answers on Drugs Manufactured at the Dewas and Paonta Sahib Facilities of Ranbaxy Laboratories, Ltd.

1. **What is FDA announcing today?**

The U.S. Food and Drug Administration has issued two Warning Letters to Ranbaxy Laboratories, Ltd., an India-based manufacturer of generic drugs, some for the U.S. market. The Warning Letters address the manufacturing conditions at two different Ranbaxy plants in India, Dewas and Paonta Sahib. FDA inspections have shown extensive deviations from U.S. current Good Manufacturing Practice (cGMP) requirements.

Additionally, the FDA has issued an Import Alert, which FDA can use to bar the import of active pharmaceutical ingredients and finished drug products from these two Ranbaxy facilities in India, unless they are shown to be in compliance with the cGMP requirements.

2. **What products are affected by today's announcement?**

Ranbaxy manufactures many drugs, and only a portion of them are made at these two plants located in Dewas and Paonta Sahib, India. At these two facilities, Ranbaxy manufactures more than 30 different generic drugs (in multiple dosage forms), such as antibiotics, anti-virals, and others, for the U.S. market.

- Drug List[1]

3. **Will there be a drug shortage if products from these two plants are no longer imported into the U.S. and what is FDA doing about it?**

Consumers should not be affected by today's actions. FDA has determined that there should be ample supply from other manufacturers to meet market demands once the Ranbaxy products are no longer available, with the exception of one drug, Ganciclovir oral capsules, an anti-viral drug. Ranbaxy is the sole supplier to the United States of this drug. FDA is generally not preventing the importation of this product to minimize any disruption to the market. However, FDA will work to ensure additional controls are put into place until the company meets U.S. current Good Manufacturing Practice (cGMP) requirements.

4. **Are my Ranbaxy medications still safe to take?**

For consumers currently taking a Ranbaxy product affected by this action, FDA strongly advises these consumers not to interrupt their drug therapy, which could have serious implications for their health. To date, FDA has no evidence of harm to any patients who have taken drugs made in these two facilities.

Today's actions are being taken as a preventive measure because the manufacturing processes at these two Ranbaxy facilities do not meet FDA's regulatory standards. By focusing on the process used to make these drugs, FDA is working to prevent the possibility that a product that does not meet its specifications could get into the hands of U.S. consumers.

Additionally, consumers should know that products from Ranbaxy's ***other*** plants ***are not affected by this action.*** FDA has inspected those facilities and to date they have met FDA standards for drug manufacturing.

5. **Have any consumers been harmed by the Ranbaxy drugs listed on the Import Alert?**

To date, FDA has no evidence of harm to any patients.

6. **Should I see my doctor if I want my prescription refilled with a different manufacturer other than Ranbaxy?**

FDA advises any consumer who is concerned about their drugs to discuss those concerns with a health care professional.

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

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