



Market Scan

FDA: Ranbaxy Botched Manufacturing

Lisa LaMotta, 09.16.08, 7:00 PM ET

The U.S. Food and Drug Administration warned the American public on Tuesday that two factories run by India-based generic drug-maker **Ranbaxy Laboratories** did not meet safety and contamination standards for manufacturing drugs.

The regulatory agency has been in discussions with Ranbaxy Laboratories for several months concerning the two facilities and the perceived deficiencies exhibited at the facilities in Dewas and Paonta Sahib. After much discussion and what it deemed inadequate responses from the drugmaker, the FDA decided to issue the warning and to encourage the confiscation of products coming from the two facilities into the United States.

Ranbaxy is one of the worlds largest providers of generic drugs, a multi-billion dollar market that has become of increasing interest to large U.S. pharmaceutical companies as their blockbuster compounds lose patent protection.

Ranbaxy makes about [30 different generic drugs](#) for the U.S. market at the two facilities. The factories allegedly were not taking the proper precautions to prevent cross-contamination between products and to assure adequate sterilization procedures. The FDA said that it does not expect shortages of any of the drugs due to the confiscation, and has determined that other suppliers should be able to meet market demand for the products.

One product, Ganciclovir Sodium, is not on the confiscation list because it is only produced by Ranbaxy and not by any of its competitors. Ganciclovir Sodium is the active ingredient in an antiviral medication that treats retinitis, the inflammation of the retina in the eye. The FDA said it will conduct additional oversight over the shipments of this medication.

The FDA assured the public that it has no evidence that any harm has been caused by any drugs that have come from the two facilities and recommends that patients continue taking their medications until they consult a healthcare professional.

"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, director of the FDA's Center for Drug Evaluation and Research.

Shares of Ranbaxy were down 13.55 Rupees (29 cents), or 3.2%, to close at 405.90 Rupees (\$8.65) in Mumbai on Tuesday before the announcement.