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U.S. Food & Drug Administration

News & Events

FDA NEWS RELEASE

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Department of Justice files consent decree of permanent injunction against Ranbaxy
Generic drug manufacturer agrees to remedy deviations from the current good manufacturing practice requirements and to correct data integrity problems at numerous facilities

The Department of Justice, on behalf of the U.S. Food and Drug Administration, has filed a consent decree of permanent injunction against generic drug manufacturer Ranbaxy in the U.S. District Court of Maryland. The consent decree was filed against Ranbaxy Laboratories, Ltd., an Indian corporation and its subsidiary Ranbaxy Inc., headquartered in Princeton, N.J. Ranbaxy Labs.' Dale Adkisson, senior vice president, head of global quality and Arun Sawhney, chief executive officer and managing director, and Ranbaxy, Inc.'s Venkatachalam Krishnan, regional director Americas, were also named as defendants. The consent decree will address outstanding current good manufacturing practice (CGMP) and data integrity issues at Ranbaxy's Paonta Sahib, Batamandi and Dewas, India facilities as well as CGMP issues at Ranbaxy Inc.'s wholly owned subsidiary Ohm Laboratories facility located in Gloversville, N.Y.

Ranbaxy's Paonta Sahib, Batamandi, and Dewas, India facilities have been on FDA import alert since 2008 and Ranbaxy has closed its Gloversville facility. The public should not be concerned that any drugs from those facilities are currently in the U.S. market. FDA recommends that patients not disrupt their drug therapy because this could jeopardize their health. Individuals who are concerned about their medications should talk with their health care professional.

The consent decree requires that Ranbaxy comply with detailed data integrity provisions before FDA will resume reviewing drug applications containing data or other information from the Paonta Sahib, Batamandi, and Dewas facilities. Specifically, Ranbaxy must:

(1) hire a third party expert to conduct a thorough internal review at the facilities and audit applications containing data from the affected facilities;

(2) implement procedures and controls sufficient to ensure data integrity in the company's drug applications; and

(3) withdraw any applications found to contain untrue statements of material fact and/or a pattern or practice of data irregularities that could affect approval of the application.

In addition, the consent decree prevents Ranbaxy from manufacturing drugs for introduction to the U.S. market and for the President's Emergency Plan for AIDS Relief (PEPFAR) Program at the Paonta Sahib, Batamandi, Dewas, and Gloversville facilities until drugs can be manufactured at such facilities in compliance with U.S. manufacturing quality standards.

"Because this company continued to violate current good manufacturing practice regulations and falsify information on drug applications, the FDA took these actions in an effort to protect consumers," said Dara Corrigan, FDA associate commissioner for regulatory affairs. "The FDA continues to be committed to protecting consumers from potentially unsafe products that may be offered on the market."

Under this agreement, once Ranbaxy has achieved compliance with the data integrity requirements, a third party expert must conduct audits of the facilities to confirm that compliance is being maintained. The company must authorize an individual to be responsible for all quality assurance and quality control activities to ensure that drugs have the required safety, identity, strength, quality, purity, and potency and are in compliance with the law and the decree. In addition, they must establish an Office of Data Reliability to conduct pre-submission audits of all applications submitted from any facility after entry of the decree.

Ranbaxy has agreed to relinquish any 180-day marketing exclusivity that it might have for three pending generic drug applications, and the firm has further agreed to relinquish any 180-day marketing exclusivity that it may have for several additional generic drug applications if it fails to meet certain decree requirements by specified dates.

The consent decree contains liquidated damages provisions to cover many potential violations of the law and the decree. In addition to a provision requiring Ranbaxy to pay $15,000 in liquidated damages for each day defendants violate the law or the decree at the facilities covered by the decree and an additional sum of $15,000 for each overall violation of the law and the decree, the decree states that: (1) if defendants distribute any drug from the facilities covered by the decree, Ranbaxy shall pay liquidated damages equal to two times the retail value of such drug, not to exceed 10 million dollars in any one calendar year; and (2) if defendants submit an untrue statement in connection with any application they file with FDA, Ranbaxy shall pay up to three million dollars in liquidated damages for each such statement, not to exceed 30 million dollars in any one calendar year.

The decree also permits FDA to order additional Ranbaxy facilities to be covered by the decree if the agency discovers through an inspection that the facility is not operating in compliance with the law and/or has serious data integrity issues.

The decree was filed on January 25, 2012, and is subject to court approval.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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