JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Wednesday, January 25, 2012

U.S. Files Consent Decree for Permanent Injunction Against Pharmaceutical Ranbaxy Laboratories

The United States has filed a consent decree for permanent injunction against the generic drug manufacturer Ranbaxy Laboratories Ltd., an Indian corporation, in the U.S. District Court for the District of Mar yland, the Department of Justice announced today. The Justice Department filed the consent decree at the request of the Food and Drug Administration (FDA).

Through investigation by the department and the FDA, the government uncovered numerous problems with Ranbaxy's drug manufacturing and testing in India and at facilities owned by its U.S. subsidiary, Ranbaxy Inc. These problems include failure to keep written records showing that drugs had been manufactured properly; failure to investigate evidence indicating that drugs did not meet their specifications; failure to adequately separate the manufacture of penicillin drugs from non-penicillin drugs in order to prevent cross-contamination; failure to have adequate procedures to prevent contamination of sterile drugs; and inadequate testing of drugs to ensure that they kept their strength and effectiveness until their expiration date.

The government also determined that Ranbaxy submitted false data in drug applications to the FDA, including the backdating of tests and the submitting of test data for which no test samples existed. All of these actions constituted violations of the federal Food, Drug and Cosmetic Act, making many of Ranbaxy's drugs adulterated, potentially unsafe and illegal to sell in the United States.

"This action against Ranbaxy is groundbreaking in its international reach – it requires the company to make fundamental changes to its plants in both the United States and India," said Tony West, Assistant Attorney General for the Justice Department's Civil Division. "Our commitment to ensuring that the drugs the American people rely on are safe, effective and manufactured according to the FDA's standards extends beyond our borders."

The consent decree filed today is unprecedented in its scope, and requires Ranbaxy to take a wide range of actions to correct its violations and ensure that they do not happen again. Among other things, the consent decree prevents Ranbaxy from manufacturing drugs for the U.S. market at certain of its facilities until those facilities can do so according to U.S. standards. To remove false data contained in Ranbaxy's past drug applications and to prevent Ranbaxy from submitting false data to FDA in the future, the consent decree requires Ranbaxy to take actions such as: hire an outside expert to conduct a thorough internal review at the affected facilities and to audit applications containing data from those facilities; withdraw any applications found to contain false data; set up a separate office of data reliability within Ranbaxy; and hire an outside auditor to audit the affected facilities in the future.

Once the consent decree is approved by the court, it becomes a court order with which Ranbaxy must comply or face contempt.

"Submitting false data to the FDA in drug applications will not be tolerated," said Mr. West. "The Department of Justice, in partnership with the FDA, will use all available tools, including civil injunction actions and consent decrees, to ensure the integrity of drug applications, and to ensure that all drugs sold in the U.S. meet U.S. standards."

"American consumers rely upon the FDA to regulate pharmaceutical drugs, and the FDA relies upon manufacturers to comply with federal standards and provide truthful information," said Rod J. Rosenstein, U.S. Attorney for the District of Maryland.

Assistant Attorney General West thanked the FDA for referring this matter to the Department of Justice. Allan Gordus, Trial Attorney, of the Consumer Protection Branch of the Justice Department, in conjunction with the U.S. Attorney's Office for the District of Maryland and Marci Norton, Senior Counsel at FDA's Office of the Chief Counsel, brought this case on behalf of the United States.

12-105 Civil Division