Department of Justice

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GENERIC DRUG MANUFACTURER RANBAXY PLEADS GUILTY AND AGREES TO PAY $500 MILLION TO RESOLVE FALSE CLAIMS ALLEGATIONS, cGMP VIOLATIONS, AND FALSE STATEMENTS TO THE FDA

WASHINGTON – In the largest drug safety settlement to date with a generic drug manufacturer, Ranbaxy USA Inc., a subsidiary of Indian generic pharmaceutical manufacturer Ranbaxy Laboratories Limited, pleaded guilty today to felony charges relating to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's manufacturing facilities in India, the Justice Department announced today. Ranbaxy also agreed to pay a criminal fine and forfeiture totaling $150 million and to settle civil claims under the False Claims Act and related State laws for $350 million.

The Federal Food, Drug and Cosmetic Act (FDCA) prohibits the introduction or delivery for introduction into interstate commerce of any drug that is adulterated. Under the FDCA, a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacturing, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current Good Manufacturing Practice (cGMP) regulations. This assures that a drug meets the requirements as to safety and has the identity and strength, and meets the quality and purity characteristics, which the drug purports or is represented to possess.

Ranbaxy USA pleaded guilty to three felony FDCA counts, and four felony counts of knowingly making material false statements to the FDA. The generic drugs at issue were manufactured at Ranbaxy's facilities in Paonta Sahib and Dewas, India. Under the plea agreement, the company will pay a criminal fine of $130 million, and forfeit an additional $20 million.

"When companies sell adulterated drugs, they undermine the integrity of the FDA's approval process and may cause patients to take drugs that are substandard, ineffective, or unsafe," said Stuart F. Delery, Acting Assistant Attorney General for the Civil Division of the Department of Justice. "We will continue to work with our law enforcement partners to ensure that all manufacturers of drugs approved by the FDA for sale in the United States, both domestic and foreign, follow the FDA guidelines that protect all of us."

"This is the largest false claims case ever prosecuted in the District of Maryland, and the nation's largest financial penalty paid by a generic pharmaceutical company for FDCA

violations," said U.S. Attorney for the District of Maryland Rod J. Rosenstein. "The joint criminal and civil settlement, which reflects many years of work by FDA agents and federal prosecutors, holds Ranbaxy accountable for a pattern of violations and should improve the reliability of generic drugs manufactured in India by Ranbaxy."

Ranbaxy USA admitted to introducing into interstate commerce certain batches of adulterated drugs that were produced at Paonta Sahib in 2005 and 2006, including Sotret, gabapentin, and ciprofloxacin. Sotret is Ranbaxy's branded generic form of isotretinoin, a drug used to treat severe recalcitrant nodular acne; gabapentin is a drug used to treat epilepsy and nerve pain; ciprofloxacin is a broad-spectrum antibiotic. In a Statement of Facts filed along with the Information, Ranbaxy USA acknowledged that FDA's inspection of the Paonta Sahib facility in 2006 found incomplete testing records and an inadequate program to assess the stability characteristics of drugs. "Stability" refers to how the quality of a drug varies with time under the influence of a variety of factors, such as temperature, humidity, and light. Such testing is used to determine appropriate storage conditions and expiration dates for the drug, as well as to detect any impurities in the drug.

Ranbaxy also acknowledged that the FDA's 2006 and 2008 inspections of the Dewas facility found the same issues with incomplete testing records and an inadequate stability program, as well as significant cGMP deviations in the manufacture of certain active pharmaceutical ingredients and finished products. Ranbaxy USA also acknowledged that in 2003 and 2005 the company was informed of cGMP violations by consultants it hired to conduct audits at the Paonta Sahib and Dewas facilities. Those cGMP violations resulted in the introduction into interstate commerce of some adulterated drugs.

Ranbaxy USA further admitted to failing to timely file required reports known to FDA as "field alerts" for batches of Sotret and gabapentin that had failed certain tests. With respect to Sotret, Ranbaxy USA was aware in January 2003 that a batch of Sotret failed an accelerated dissolution stability test but continued to distribute the batch into the United States for another 13 months. With respect to gabapentin, Ranbaxy USA was aware at various times between June and August 2007 that certain batches of gabapentin were testing out-of-specification, had unknown impurities, and would not maintain their expected shelf life. Nevertheless, Ranbaxy USA did not notify FDA and institute a voluntary recall until October 2007.

Ranbaxy USA also admitted to making false, fictitious, and fraudulent statements to the FDA in Annual Reports filed in 2006 and 2007 regarding the dates of stability tests conducted on certain batches of Cefaclor, Cefadroxil, Amoxicillin, and Amoxicillin and Clavulanate Potassium, which were manufactured at the Dewas facility. Ranbaxy USA was found to have conducted stability testing of certain batches of these drugs weeks or months after the dates reported to FDA. In addition, instead of conducting some of the stability tests at prescribed intervals months apart, the tests were conducted on the same day or within a few days of each other. This practice resulted in unreliable test results regarding the shelf life of the drugs. Ranbaxy USA also acknowledged that drug samples waiting to be tested were stored for unknown periods of time in a refrigerator, which did not meet specified temperature and humidity ranges for an approved stability chamber, and that this was not disclosed to the FDA.

The criminal case is *U.S. v. Ranbaxy USA, Inc.*, JFM-13-CR-0238 (D. Md.).

Under the civil settlement, Ranbaxy has agreed to pay an additional $350 million to resolve allegations that it caused false claims to be submitted to government health care programs between April 1, 2003, and September 16, 2010, for certain drugs manufactured at the Paonta Sahib and Dewas facilities. The United States contends that Ranbaxy manufactured, distributed, and sold drugs whose strength, purity, or quality differed from the drug's specifications or that were not manufactured according to the FDA-approved formulation. The United States further contends that, as a result, Ranbaxy knowingly caused false claims for those drugs to be submitted to Medicaid, Medicare, TRICARE, the Federal Employees Health Benefits Program, the Department of Veterans Affairs, and the U.S. Agency for International Development (USAID), which administers the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

The federal government's share of the civil settlement amount is approximately $231.8 million, and the remaining $118.2 million will go to the states participating in the agreement.

The civil settlement resolves a lawsuit filed in U.S. District Court for the District of Maryland under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. As part of today's resolution, the whistleblower, Dinesh Thakur, a former Ranbaxy executive, will receive approximately $48.6 million from the federal share of the settlement amount. The case is *U.S. ex rel. Thakur v. Ranbaxy Laboratories Limited*, Case No. JFM-07-962 (D. Md.).

With the exception of the allegations to which Ranbaxy pleaded guilty in the Criminal Information, there has been no determination of liability as to the claims settled by the civil agreement.

Last year, FDA and Ranbaxy agreed to an injunction that prevents drugs produced at the Paonta Sahib and Dewas facilities from entering the U.S. market until the facilities have been brought into full compliance with the FDCA and its implementing regulations. Since September 16, 2008, when the FDA placed drugs from those facilities on an Import Alert, Ranbaxy has not imported drugs from those facilities into the U.S. In addition, the injunction requires Ranbaxy to review and verify data contained in Ranbaxy's past drug applications to the FDA. *United States v. Ranbaxy Laboratories, Ltd., et al.*, Case No. JFM-12-250 (D. Md).

"The FDA expects that companies will comply with the cGMP requirements mandated by law so that consumers can be assured that their medical products are safe and pure," said John Roth, director of the FDA's Office of Criminal Investigations. "The investigation that led to this settlement uncovered evidence showing that certain lots of specific drugs produced at the Paonta Sahib facility were defective, in that their strength differed from, or their purity or quality fell below, that which they purported to possess. The FDA and its law enforcement partners will continue to aggressively pursue companies and their executives who erode public confidence in

the quality and safety of medical products by distributing products that do not comply with the law."

"I would like to express my appreciation for the exceptional work of our investigators and that of their FDA and Department of Justice partners," said Michael G. Carroll, USAID Deputy Inspector General. "This settlement represents the culmination of years of investigative effort and signals our continuing commitment to the integrity of U.S. government systems and our determination to hold those who seek to defraud or mislead to account."

The criminal case was prosecuted by the U.S. Attorney's Office for the District of Maryland and the Civil Division's Consumer Protection Branch. The civil settlement was negotiated by the U.S. Attorney's Office for the District of Maryland and the Civil Division's Commercial Litigation Branch. The case was investigated by agents from the FDA's Office of Criminal Investigations and USAID's Office of Inspector General. The FDA's Office of Chief Counsel, HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division, and the National Association of Medicaid Fraud Control Units also provided assistance.

This criminal and civil resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than $10.3 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 are over $14.3 billion.

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