

Ranbaxy may face trouble in manufacturing drugs in US

Washington, January 26: In an unprecedented move, the US Justice Department has sought a permanent injunction against Ranbaxy, a move that will require the Indian pharmaceutical major to make fundamental changes to its plants both in the US and India and would prevent it from manufacturing drugs at certain facilities in the US.

The Justice Department cited violations of manufacturing standards and problems with submitted data in a consent decree for permanent injunction filed in court against the company.

"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, after it filed the consent decree at the request of the Food and Drug Administration (FDA).

"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," West said.

The consent decree filed yesterday 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, said the Justice Department.

Among other things, the consent decree seeks to prevent Ranbaxy from manufacturing drugs for the US market at certain of its facilities until those facilities can do so according to US standards.

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

Citing false data in Ranbaxy's past drug applications and the to prevent it from submitting false data in the future, the consent decree requires Ranbaxy to take a number of actions. There was no immediate reaction from Ranbaxy.

These include hiring 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, the Justice Department said.

"Submitting false data to the FDA in drug applications will not be tolerated," said 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 US meet US standards," he added.

~~Through investigation by the department and the FDA, the US government said it uncovered numerous~~

problems with Ranbaxy's drug manufacturing and testing in India and at facilities owned by its US 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 Justice Department said.

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, the Justice Department said.

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