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FDA Takes New Regulatory Action Against Ranbaxy's Paonta Sahib Plant in India

Agency halts review of drug applications from plant due to evidence of falsified data; invokes Application Integrity Policy

The U.S. Food and Drug Administration today announced that a facility owned by India-based Ranbaxy Laboratories falsified data and test results in approved and pending drug applications. The facility, Paonta Sahib, has been under an FDA Import Alert since September 2008.

The FDA is continuing to investigate this matter to ensure the safety and efficacy of marketed drugs associated with Ranbaxy's Paonta Sahib site. To date, the FDA has no evidence that these drugs do not meet their quality specifications and has not identified any health risks associated with currently marketed Ranbaxy products.

In the meantime, the 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 affected applications are for drugs that fall into three categories:

- Approved drugs made at the Paonta Sahib site for the U.S. market;
- Drugs pending approval at the FDA that are not yet marketed; and
- Certain drugs manufactured in the United States that relied on data from the Paonta Sahib facility.

“Companies must provide truthful and accurate information in their marketing applications,” said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research (CDER). “The American public expects and deserves no less.”

To address the falsified data, the FDA has invoked its Application Integrity Policy (AIP) against the Paonta Sahib facility. The AIP is invoked when a company's actions raise

significant questions about the integrity of data in drug applications. This AIP covers applications that rely on data generated by the Paonta Sahib facility only.

Under the AIP, the FDA has asked Ranbaxy to cooperate with the agency to resolve the questions of data integrity and reliability. This would include implementing a Corrective Action Operating Plan (CAOP) to provide assurance of the integrity and reliability of data from the Paonta Sahib facility. A CAOP includes, but is not limited to, conducting a third-party independent audit of applications associated with Paonta Sahib.

When the AIP is implemented, the FDA stops all substantive scientific review of any new or pending drug approval applications that contain data generated by the Paonta Sahib facility.

“The FDA’s investigations revealed a pattern of questionable data raising significant questions regarding the reliability of certain applications, and this warrants applying the Application Integrity Policy,” said Deborah Autor, director of CDER’s Office of Compliance. “Today’s action reflects the FDA’s continued vigilance and its steadfast commitment to safeguarding the public’s health.”

On Sept. 16, 2008, the FDA issued two warning letters and instituted an Import Alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy’s Dewas, Paonta Sahib and Batamandi Unit facilities due to violations of U.S. current Good Manufacturing Practices requirements. That action barred the commercial importation of 30 different generic drugs into the United States and remains in effect.