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FDA, Justice Department take action against McNeil-PPC Inc.

Charged with manufacturing and distributing OTC drugs in violation of federal law

The U.S. Food and Drug Administration announced today that a consent decree of permanent injunction has been filed against McNeil-PPC and two of its officers for failing to comply with current good manufacturing practice requirements as required by federal law. The action prevents McNeil, a subsidiary of Johnson & Johnson, from manufacturing and distributing drugs from its Fort Washington, Pa., facility until the FDA determines that its operations are compliant with the law.

McNeil Consumer Healthcare Division's Vice President of Quality and the company's Vice President of Operations for OTC Products also were named defendants in the consent decree, filed with the U.S. District Court for the Eastern District of Pennsylvania in Philadelphia on March 10, 2011.

The decree also requires McNeil to adhere to a strict timetable to bring its facilities in Las Piedras, Puerto Rico, and Lancaster, Pa., into compliance.

Dara A. Corrigan, the FDA's associate commissioner for regulatory affairs said, "This FDA drug safety enforcement action is aimed at protecting the public health."

FDA inspections at McNeil's Fort Washington, Las Piedras, and Lancaster facilities from 2009 to 2010 found violations of the Federal Food, Drug, and Cosmetic Act. The Act requires drug companies to follow current good manufacturing practice requirements.

"This is a strong, but necessary, step to ensure that the products manufactured by this company meet federal standards for quality, safety and purity," said Deborah Autor, director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research.

Manufacturing deficiencies at McNeil's facilities have resulted in several extensive recalls, including an April 30, 2010, recall of lots of several liquid products such as children's Tylenol, Motrin, Zyrtec, and Benadryl products. In January 2010, the FDA issued a Warning Letter to McNeil's Consumer Healthcare Division regarding violations identified at McNeil's Las Piedras facility.

The decree, filed by the U.S. Department of Justice's Office of Consumer Litigation and the U.S. Attorney's Office for the Eastern District of Pennsylvania, requires McNeil to destroy all drugs under McNeil's control that have been recalled from the Fort Washington, Las Piedras, and Lancaster facilities since December 2009. McNeil also must retain an independent expert to inspect the Fort Washington, Las Piedras, and Lancaster facilities to determine whether the violations have been

corrected, and to ensure that adequate manufacturing processes are in place. After expert certification, the FDA will determine if the facilities are in compliance.

If the defendants violate the decree, the FDA may order McNeil to cease manufacturing, recall products, and take other corrective action, including levying fines of $15,000 for each day and an additional $15,000 for each violation of the law, up to $10 million annually.

The decree becomes effective when it has been entered by the court.

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