[redacted]

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE Tuesday, March 10, 2015

McNeil-PPC Inc. Pleads Guilty in Connection with Adulterated Infants' and Children's Over-the-Counter Liquid Drugs

McNeil-PPC Inc. entered a guilty plea in Federal District Court in Philadelphia today to one count of an information charging the company with delivering for introduction into interstate commerce adulterated infants' and children's over-the-counter (OTC) liquid medicines, the Department of Justice announced today. As part of the criminal resolution, McNeil, a wholly owned subsidiary of Johnson & Johnson, agreed to pay a criminal fine of $20 million and forfeit $5 million.

Acting Assistant Attorney General Benjamin C. Mizer of the Justice Department's Civil Division and First Assistant U.S. Attorney Louis D. Lappen of the Eastern District of Pennsylvania today announced the filing of a criminal Information against McNeil for delivering for introduction into interstate commerce infants' and children's liquid OTC drugs that were adulterated. According to the criminal charge, the infants' and children's liquid medicines were adulterated because they were not manufactured, processed, packed or held in conformance with current Good Manufacturing Practices (cGMP), in violation of the federal Food, Drug and Cosmetic Act (FDCA).

The U.S. District Court for the Eastern District of Pennsylvania accepted McNeil's guilty plea.

In addition to McNeil's guilty plea, McNeil remains subject to a permanent injunction entered by the U.S. District Court in 2011, requiring the company, among other things, to make remedial measures before reopening its manufacturing facility in Fort Washington, Pennsylvania.

"McNeil's failure to comply with current good manufacturing practices is seriously troubling," said Acting Assistant Attorney General Mizer. "The Department of Justice will continue to be aggressive in pursuing and punishing companies such as McNeil that disregard a process designed to assure quality medicines, especially OTC drugs for infants and children."

"The law requires that drugs be produced under the most rigorous of quality standards," said First Assistant U.S. Attorney Lappen. "When companies fail to exercise the vigilance that the law demands, they will held be accountable. Drug companies should be aware that failing to adhere to good

manufacturing practices subjects them to penalties and prosecution."

According to the information, the OTC liquid drugs manufactured by McNeil at its Fort Washington facility, including Infants' and Children's Tylenol and Infants' and Children's Motrin, were bottled on four lines of machinery dedicated to liquid formulations. As alleged in the information, on or about May 1, 2009, McNeil received a complaint from a consumer regarding the presence of "black specks in the liquid on the bottom of the bottle" of Infants' Tylenol. According to the information, the foreign material was later identified as including nickel/chromium-rich inclusions, which were not intended ingredients in this OTC liquid drug. In connection with receiving this consumer complaint, McNeil did not initiate or complete a Corrective Action Preventive Action (CAPA) plan, as alleged in the charging document.

The information alleges numerous other instances in which McNeil found metal particles in bottles of Infants' Tylenol at its Fort Washington facility but failed to initiate or complete a CAPA. According to the information, during a 2010 Inspection of McNeil's Fort Washington facility, the U.S. Food and Drug Administration (FDA) asked McNeil for a list with all non-conformances for particles and the associated OTC drug batches that had occurred since an FDA inspection in 2009. As noted in the information, this document revealed 30 batches of OTC liquid drugs, including Infants' Tylenol, Children's Tylenol, and Children's Motrin. During the 2010 inspection, the FDA asked McNeil for the CAPA plan covering the particles and foreign material found in the Infants' and Children's OTC drugs, and a McNeil employee confirmed that McNeil did not have such a CAPA plan.

On or about April 30, 2010, McNeil Consumer Health Care, a division of McNeil, in consultation with the FDA, announced that the company was recalling all lots of certain unexpired Infants' and Children's OTC drugs manufactured at McNeil's Fort Washington facility and distributed in the United States and other countries around the world. McNeil's recall included, but was not limited to, Infants' and Children's Tylenol and Infants' and Children's Motrin. According to a press release issued by McNeil on April 30, 2010, some of the recalled OTC drugs "may contain tiny particles."

The FDCA prohibits causing the introduction or delivery for introduction into interstate commerce of any adulterated drug. Under the law, a drug is adulterated if the methods used in, or the facilities and controls used for, the manufacture, processing, packing, labeling, holding and distribution of drugs and components were not in conformance with cGMP requirements for drugs. Drugs not manufactured, processed, packed, labeled, held and distributed in conformance with cGMP requirements are adulterated as a matter of federal law, without any showing of actual defect.

"Drug quality – and especially with the medicines we give our children – is of paramount concern to the FDA," said Commissioner Margaret A. Hamburg M.D. of the FDA. "The FDA expects manufacturers to have systems in place that will quickly discover and correct problems with medical products before they enter the U.S. marketplace. Today's guilty plea holds accountable those corporations who risk jeopardizing the public health by not adhering to the high standards set for drug manufacturers."

Acting Assistant Attorney General Mizer and First Assistant U.S. Attorney Lappen commended the investigative efforts of the FDA's Office of Criminal Investigations. The government is represented in this case by Assistant Director Jeffrey Steger and Trial Attorney Kathryn Drenning of the Civil Division's Consumer Protection Branch and Assistant U.S. Attorney Mary Beth Leahy of the Eastern District of Pennsylvania, with the assistance of Associate Chief Counsel for Enforcement Laura Pawloski of the Department of Health and Human Services' Office of General Counsel's Food and Drug Division.

Attachment(s):
Download mcneil_information.pdf
Download united_states_plea_and_sentencing_memorandum_with_plea_agreement.pdf

Topic(s):
Consumer Protection

Component(s):
Civil Division

Press Release Number:
15-289

Updated March 10, 2015