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PRESS RELEASE

Attorney General Frosh and 42 Other State Attorneys General Settle Claims Regarding the Quality of Over-the-Counter Drugs Marketed and Sold by Johnson & Johnson Consumer Inc. and Johnson & Johnson

Companies to Pay $33 Million as Part of Multi-State Settlement for Alleged Unfair and Deceptive Marketing of Over-the Counter Drugs

BALTIMORE, MD (May 24, 2017) – Maryland Attorney General Brian E. Frosh announced today that he, along with 42 other State Attorneys General, have reached a $33 million settlement with Johnson & Johnson Consumer Inc., Johnson & Johnson, and McNeil Consumer Healthcare Division (collectively "McNeil"), for alleged unfair and deceptive marketing of over-the-counter drugs. The states entered into a Consent Judgment with the companies.

McNeil Consumer Healthcare Division, now a division of Johnson & Johnson Consumer Inc., a subsidiary of Johnson & Johnson, marketed and distributed over-the-counter drugs. According to the complaint filed today, between 2009 and 2011, McNeil put on the market certain batches of over-the-counter drugs, including Tylenol, Motrin, Benadryl, St. Joseph Aspirin, Sudafed, Pepcid, Mylanta, Rolaids, Zyrtec, and Zyrtec Eye Drops, that failed to comply with federal standards and therefore were deemed adulterated as a matter of federal law.

McNeil's alleged quality control lapses resulted in recalls of more than 2,000 product lots of over-the-counter drugs, several of which are indicated for infant or pediatric use. The complaint alleges that McNeil violated state consumer protection laws by (1) misrepresenting its compliance with federally mandated current Good Manufacturing Practices (cGMP) and the quality of its over-the-counter drugs, (2) representing that these over-the-counter drugs had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they did not have, and (3) failing to disclose material facts about the quality of its over-the-counter drugs and its compliance with current Good Manufacturing Practices. According to admissions that McNeil made in a federal court guilty plea, McNeil failed to initiate corrective action when it learned of foreign material, particulate matter and/or contamination in multiple batches of its over-the-counter drugs.

"We rely on the drug companies to follow good manufacturing practices," said Attorney General Frosh. "Consumers have a right to know if there might be a problem with the drugs they are purchasing, especially those we give to our children."

The Consent Judgment resolves the complaint's allegations and requires McNeil to ensure that its marketing and promotional practices do not unlawfully promote over-the-counter drugs. Specifically, McNeil shall not:

- Represent on its websites that McNeil's over-the-counter drug production facilities meet current Good Manufacturing Practices as outlined by the FDA if McNeil has had a Class I or Class II recall of over-the-counter drugs within the prior twelve (12) months at its Fort Washington, Pennsylvania or Las Piedras, Puerto Rico manufacturing facilities. Class I recalls involve situations in which there is a reasonable probability that the use of or exposure to the drug product will cause serious adverse health consequences or death. Class II recalls involve situations in which use of or exposure to the drug product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote;

- Fail to follow its internal standard operating polices regarding whether to open a Corrective Action/Preventive Action plan (CAPA) during the manufacture of an over-the-counter drug; and

- Fail to provide information to participating Attorneys General within sixty (60) days of a written request regarding the identity of wholesalers or warehouses to which any over-the-counter drugs that were subject to a recall were distributed in their State.

Pennsylvania and Texas led the Executive Committee, which also includes Attorney General Frosh and the Attorneys General from Arizona, Delaware, District of Columbia, Florida, Kentucky, Massachusetts, Montana, New Jersey, and Ohio.

Also participating in the settlement are Alaska, Arkansas, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Kansas, Louisiana, Maine, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, Washington, West Virginia, and Wisconsin.