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NONPRESCRIPTION MEDICATIONS

FDA issues guidances for OTC labeling of aspirin and acetaminophen

On January 10, the FDA issued 2 guidances relating to OTC aspirin and acetaminophen products. The aspirin guidance was issued as a draft for comments over the next 60 days, and dealt with a recommended statement when the aspirin product is labeled with "cardiovascular related imagery," such as a stethoscope surrounding a heart. OTC aspirin products are marketed under the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for OTC Human Use, issued in 1988. The TFM does not envision labeling for use in secondary prevention of cardiovascular events, although the approved professional labeling (21 CFR 343.80) does so. In the guidance, the FDA notes that §343.80 contains indications for "reducing the risk of a second heart attack or stroke in patients who have already experienced a cardiovascular or cerebrovascular event or for patients with existing coronary artery disease ..." However, such use also has side effects including GI bleeding, cerebral bleeding, kidney failure, and hemorrhagic strokes. Although the FDA has never formalized rulemaking requiring OTC aspirin products to contain information on cardiovascular use, it does believe that placing cardiovascular related imagery on the product label implies a use not authorized in the TFM. In the proposed guidance, the FDA asserts it will not act against a manufacturer of OTC aspirin products with cardiovascular related imagery if the labeling also includes the statement, "Consult your healthcare provider before using this product for your heart." [USDHHS, FDA. Recommended statement for over-the-counter aspirin-containing drug products labeled with cardiovascular related imagery. Guidance for industry. 2017 Jan 10; http://bit.ly/2iGovjU]

The FDA published a final guidance recommending a warning on acetaminophen OTC labels concerning serious skin reactions (e.g., Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis). In 2013, FDA required manufactures holding NDAs or ANDAs for acetaminophen-containing products to include warnings about serious skin reactions in their labeling, and the guidance notes that those changes have now been made. This guidance is directed at manufacturers who are marketing acetaminophen-containing products under the 1988 TFM, and informs them that FDA will not act against them if their labeling contains the following language in the Warnings section of the DRUG FACTS label: "Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may contain [bullet] skin reddening [bullet] blisters [bullet] rash. If a skin reaction occurs, stop use and seek medical help right away." [DHHS, FDA. Recommended warning for over-the-counter acetaminophen-containing drug products and labeling statements regarding serious skin reactions. Guidance for industry. 2017 Jan 10; http://bit.ly/2j6OPqm]