Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2017
Compliance

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I. INTRODUCTION AND SCOPE

This guidance applies to single-ingredient aspirin, buffered aspirin, and aspirin in combination with an antacid, labeled with cardiovascular related imagery marketed under the Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products for OTC Human Use (53 FR 46204, November 16, 1988). FDA is aware that some over-the-counter (OTC) aspirin drug products are marketed with cardiovascular related images, such as heart symbols, which suggest or imply that the products are intended for use in the prevention of cardiovascular events. Secondary prevention of cardiovascular events is permitted as an indication for aspirin in professional labeling (21 CFR 343.80). This guidance is intended to promote the safe use of OTC aspirin drug products by encouraging drug manufacturers, packagers, and labelers marketing aspirin drug products with cardiovascular related imagery to include a statement that reminds consumers to talk to their healthcare provider before using aspirin for the professional indication of secondary prevention of cardiovascular events.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Aspirin is a common active ingredient in many prescription and OTC drug products. Most OTC aspirin drug products are currently marketed pursuant to the TFM for IAAA Drug Products (53 FR 46206, Nov. 16, 1988) for the temporary relief of minor aches and pains associated with a

[1] This guidance has been prepared by the Office of Unapproved Drugs and Labeling Compliance in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

cold, headache, backache, toothache, premenstrual and menstrual cramps; minor pain of arthritis; and reduction in fever.

In addition to the OTC conditions of use in the IAAA TFM, FDA regulations at § 343.80 also contain professional labeling about cardiovascular uses of aspirin directed at healthcare practitioners (63 FR 56802, October 23, 1998). The cardiovascular indications for aspirin under professional labeling include 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 such as angina or a history of a coronary bypass or coronary angioplasty. However, such long-term aspirin therapy has a number of side effects, such as stomach bleeding, bleeding in the brain, kidney failure, and other kinds of strokes.

In the IAAA TFM, FDA proposed a labeling statement recommending that consumers consult a physician about the professional indications of aspirin, due to the potential side effects of long-term aspirin therapy (53 FR 46204, November 16, 1988).

In addition, FDA published a proposed rule on October 20, 1993, that would require OTC drug products that contain aspirin, buffered aspirin, or aspirin in combination with an antacid to bear a statement advising consumers to consult a physician before taking these products for cardiovascular uses (58 FR 54224, October 20, 1993). However, this proposed rule has not been finalized.

III. DISCUSSION AND POLICY

After publication of the professional labeling regulation for aspirin, some OTC aspirin labels[2] were modified to include cardiovascular related imagery (e.g., heart image, Electrocardiography graphic, stethoscope around a heart image). However, the final rule for IAAA products at § 343.80 authorizes labeling for cardiovascular events only in professional labeling directed to healthcare professionals.

Because of the potential side effects associated with long-term aspirin therapy, FDA recommends that any cardiovascular related imagery on OTC aspirin labels be accompanied by a statement that reminds consumers to talk to their healthcare provider before using aspirin for the professional indication of secondary prevention of cardiovascular events. More specifically, FDA does not intend to take action against manufacturers of single-ingredient aspirin, buffered aspirin, and aspirin in combination with an antacid, marketed pursuant to the TFM for IAAA Drug Products because the product label includes cardiovascular related imagery such as the heart image, if the label also includes the following statement:

> Consult your healthcare provider before using this product for your heart.

[2] In this draft guidance, the term "label" means the written, printed, and graphic matter upon the immediate container and upon the outside container or wrapper of the retail package of an OTC aspirin drug product. See section 201(k) of the Federal Food, Drug, and Cosmetic Act.

This recommended statement should appear in reasonable proximity to the cardiovascular related imagery and with sufficient prominence in 6-point type size font on the principal display panel (PDP).

This guidance does not address alternative language, other health imagery, or other cardiovascular claims included on consumer directed label or labeling which may otherwise misbrand the product.