location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On March 13, 2017, from 9:15 a.m. to 5 p.m., and on March 14, 2017, from 8 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before February 27, 2017, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 10:30 a.m. on March 14, 2017. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 16, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 17, 2017.

Closed Committee Deliberations: On March 13, 2017, from 8 a.m. to 9:15 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)). During this session, the committees will discuss the premarketing drug development program of an extended-release opioid product.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–0067. The docket will close on March 10, 2017. Comments received on or before February 27, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 6, 2017.

Janice M. Soreth,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2017–00463 Filed 1–10–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0529]

Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery.'' The guidance is intended to promote the safe use of nonprescription (also referred to as over-the-counter or 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 health care provider before using aspirin for their heart.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(a)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 13, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0529 for ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential

information that you do not wish to be made publicly available submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Emily Baker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5203, Silver Spring, MD 20993–0002, 301–796–7524, *Emily.Baker@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery.'' Aspirin is a common active ingredient in many prescription and OTC drug products. Most OTC aspirin drug products are currently marketed pursuant to the Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products (53 FR 46204, November 16, 1988) for the temporary relief of minor aches and pains associated with a 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 (21 CFR 343.80) also contain professional labeling about cardiovascular uses of aspirin directed at health care practitioners (63 FR 56802, October 23, 1998). After publication of the professional labeling regulation for aspirin, some OTC aspirin labels 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 health care 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 health care provider before using aspirin for the professional indication of secondary prevention of cardiovascular events. Therefore, this draft guidance provides that 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 (*e.g.,* heart image, electrocardiography graphic, stethoscope around a heart image) if the label also includes language as described in the draft guidance recommending that patients talk to a health care professional before taking aspirin for cardiovascular uses and the product is otherwise marketed in accordance with the TFM.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The recommendations in this draft guidance are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 5, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00374 Filed 1–10–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0198]

Current Good Manufacturing Practice Requirements for Combination Products; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry and FDA staff entitled ''Current Good Manufacturing Practice Requirements for Combination Products.'' The guidance describes and explains the document on current good manufacturing practice (CGMP) requirements for combination products, which published in the **Federal Register** of January 22, 2013, and includes general considerations for CGMP compliance as well as analysis of hypothetical scenarios.