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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular Related Imagery.''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.

DATES: Submit either electronic or written comments on this guidance at any time.

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–2015–D–0198 for ''Current Good Manufacturing Practice Requirements for Combination Products; Final Guidance for Industry and FDA Staff.'' 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 guidance document entitled ''Current Good Manufacturing Practice Requirements for Combination Products'' to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns or John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled ''Current Good Manufacturing Practice Requirements for Combination Products.'' The guidance provides background on combination products, including an overview of the document on CGMP requirements for combination products, which published in the **Federal Register** of January 22, 2013 (78 FR 4307), and the role of the lead center and other Agency components with respect to combination product CGMP issues. The guidance addresses general considerations for CGMP requirements for combination products and the purpose and content of specific CGMP provisions addressed in part 4 (21 CFR part 4). The guidance also contains hypothetical scenarios intended to clarify how to comply with certain CGMP requirements addressed in part 4 by presenting compliance considerations for specific types of combination products.

FDA carefully considered the comments received on the draft guidance, and, where possible, has incorporated into the final guidance additional detailed discussion of how the requirements apply and acceptable CGMP compliance approaches. FDA encourages combination product manufacturers to contact the lead Center for their combination product and/or the Office of Combination Products if they have questions on CGMP compliance or approaches they are considering for meeting CGMP requirements.

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM429304.pdf.*

III. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We note that the information collected under the underlying CGMP regulations for drugs, devices, and biological products, including current good tissue practices for human cells, tissues, and cellular and tissue-based products, found at parts 211, 820, 600 through 680, and 1271 (21 CFR parts

211, 820, 600 through 680, and 1271), have already been approved and are in effect. The provisions of part 211 are approved under OMB control number 0910–0139. The provisions of part 820 are approved under OMB control number 0910–0073. The provisions of parts 606 and 640 are approved under OMB control number 0910–0116. The provisions of part 610 are approved under OMB control numbers 0910–0116 and 0910–0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910–0543.

Dated: January 6, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00411 Filed 1–10–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Nurse Anesthetist Traineeship (NAT) Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 10, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Nurse Anesthetist Traineeship (NAT) Program Application

OMB No.: 0915–0374—Revision

Abstract: HRSA provides advanced education nursing training grants to educational institutions to increase the numbers of Nurse Anesthetists through the NAT Program. The NAT Program is authorized by Section 811 of the Public Health Service (PHS) Act (42 U.S.C. 296j). The NAT Tables request information on program participants from the previous year, including the number of enrollees; number of enrollees/trainees supported; number of graduates; number of graduates supported; projected data on the number of enrollees/trainees and graduates; the degree program (Master's and Doctoral) the Nurse Anesthesia student trainees are enrolling into and/or from which enrollees/trainees are graduating; and the distribution of Nurse Anesthetists who practice in underserved, rural, and/or public health practice settings.

Need and Proposed Use of the Information: Funds appropriated for the NAT Program are distributed among eligible institutions based on a formula, as permitted by PHS Act Section 806(e)(1). HRSA uses the data from the NAT Tables to determine the award amount, ensure compliance with programmatic and grant requirements, and provide information to the public and Congress.

HRSA is streamlining the data collection forms from three tables to two tables by making the following changes:

- *Table 1—NAT:* Enrollment, Traineeship Support, Graduates, Graduates Supported, and Projected Data will no longer capture data by students in the first 12 months of study and students beyond the first 12 months of study in the program. Data will continue to be captured by Master's and Doctoral students.
- *Table 2A—NAT:* Graduate Data—Rural, Underserved, or Public Health is now Table 2 due to the elimination of Table 2B. There are no other changes to this form.
- *Table 2B—NAT:* Graduates Supported by Traineeship Data—Rural, Underserved, or Public Health (7/01/15–6/30/16) will be discontinued.

Rationale: The NAT Program Specific Data Forms will be revised to streamline the process and capture only essential data for use in the formula calculation, ensure grantee compliance, and measure and evaluate the program.

Likely Respondents: Eligible applicants are education programs that provide registered nurses with full-time nurse anesthesia education and are accredited by the Council on Accreditation (COA) of Nurse Anesthesia Educational Programs. Such programs may include schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities authorized by the Secretary to confer degrees to registered nurses for full-time nurse anesthesia education. Faith-based and community-based organizations, Tribes, and tribal organizations may apply for these funds if otherwise eligible. In addition to the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau may apply.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.