constitutes new safety information; what procedures are involved in requiring safety labeling changes; and how FDA will enforce the requirements for safety labeling changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on implementation of section 505(o)(4) of the FD&C Act. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0734. This guidance also refers to previously approved collections of information. Specifically, the guidance describes: Labeling supplements for NDAs, ANDAs, and BLAs submitted under 21 CFR 314.70, 314.71, 314.97, and 601.12; and the content and format of prescription drug labeling submitted under 21 CFR 201.56 and 201.57. These collections of information are subject to review by OMB under the PRA and are approved under OMB control numbers 0910–0001, 0910–0338, and 0910–0572. Section V of the guidance refers to the guidance entitled ''Formal Dispute Resolution: Appeals Above the Division Level,'' which describes collections of information approved under OMB control number 0910–0430.

IV. Electronic Access

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

Dated: July 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18236 Filed 7–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 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–XXXX—New.

Abstract: The Health Resources and Services Administration (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 governed by Title VIII, Section 811(a)(2) of the Public Health Service Act, (42 U.S.C. 296j(a)(2)), as amended by Section 5308 of the Patient Protection and Affordable Care Act, Public Law 111–148. The NAT application will use the SF–424 R&R Short Form which includes the Project Abstract, Program Narrative, NAT Attachments and the NAT Tables. The application and proposed NAT Tables will request information on program participants such as the number of enrollees, number of enrollees/trainees supported, number of graduates, number of graduates supported, projected data on enrollees/trainees and graduates for the previous fiscal year, the types of programs they are enrolling into and/or from which enrollees/trainees are graduating, and the distribution of Nurse Anesthetists to practice in underserved, rural, 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. NAT award amounts are based on enrollment and graduate data and two funding factors (Statutory Funding Preference and Special Consideration) reported on the NAT Tables. HRSA will use the data from the application, specifically the NAT Tables to determine the award, ensure programmatic compliance, and provide information to the public and Congress.

Likely Respondents: Eligible applicants are schools of nursing, nursing centers, academic health centers, state or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit an application and are accredited for the provision of nurse anesthesia educational program by designated accrediting organizations. Eligible applicants must be accredited by the Council on Accreditation (COA) of Nurse Anesthesia Educational Programs of the American Association of Nurse Anesthetists. The school must be located in the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, Guam, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau.

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.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
NAT Application including the NAT Attachments and NAT Tables	100	1	100	6	600
Total	100	1	100	6	600

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: July 24, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–18310 Filed 7–29–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 2013.

The National Advisory Committee on Rural Health will convene its seventy-fourth meeting in the time and place specified below:

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Time: September 4, 2013, 9:00 a.m.–5 p.m. September 5, 2013, 9:00 a.m.–5 p.m. September 6, 2013, 8:45 a.m.–11:00 a.m.

Place: Holiday Inn Bozeman, 5 East Baxter Lane, Bozeman, MT 59715, (406) 587–4561.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Wednesday morning, September 4, at 9:00 a.m., the meeting will be called to order by the Chairperson of the Committee: the Honorable Ronnie Musgrove. The Committee will be examining outreach, enrollment and education efforts for the rural population in regards to the Health Insurance Marketplaces which will open this fall. The Committee will also examine the intersection of human service delivery and poverty in rural communities. The day will conclude with a period of public comment at approximately 5:00 p.m.

Thursday morning, September 5, at approximately 9:00 a.m., the Committee will break into Subcommittees and depart for site visits to health care and human services providers in Montana. One panel from the Health Subcommittee will visit Community Health Partners in Livingston, Montana. Another panel from the Health Subcommittee will visit Wheatland Memorial Healthcare in Harlowton, Montana. The Human Services Subcommittee will visit the Human Resource Development Council, in Bozeman, Montana. The day will conclude at the Holiday Inn Bozeman with a period of public comment at approximately 4:30 p.m.

Friday morning, September 6, at 8:45 a.m., the Committee will summarize key findings from the meeting and develop a work plan for the next quarter and the following meeting.

FOR FURTHER INFORMATION CONTACT: Steve Hirsch, MSLS, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 5A–05, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, or fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Kristen Lee at the Office of Rural Health Policy (ORHP) via telephone at (301) 443–0835 or by email at *klee1@hrsa.gov*. The Committee meeting agenda will be posted on ORHP's Web site *http://www.hrsa.gov/advisorycommittees/rural/*.

Dated: July 24, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–18308 Filed 7–29–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the National Advisory Neurological Disorders and Stroke Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and