

that a collection of information entitled "Guidance on Reagents for Detection of Specific Novel Influenza A Viruses" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On March 20, 2013, the Agency submitted a proposed collection of information entitled "Guidance on Reagents for Detection of Specific Novel Influenza A Viruses" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0584. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 24, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0164]

#### Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizing FDA to require certain drug and biological product application holders to make safety-related labeling changes based upon new safety information that becomes available after the drug or

biological product is approved under the FD&C Act or the Public Health Service Act (the PHS Act). This final guidance provides information on the implementation of section 505(o)(4) of the FD&C Act, including a description of the types of safety labeling changes that ordinarily might be required under this section; how FDA plans to determine what constitutes new safety information; the procedures involved in requiring safety labeling changes; and enforcement of the requirements for safety labeling changes.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Kristen Everett, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993-0002, 301-796-0453; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a guidance for industry entitled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD&C Act." In the past, FDA has requested that holders of applications for approved products make labeling changes related to safety after approval to address serious risks. In most cases, application holders

responded to these requests by negotiating appropriate language with FDA staff to address the concerns and then submitting a supplement or amended supplement to obtain approval of the change. However, negotiations were often protracted, and FDA had few tools available at its disposal to end negotiations and require the changes. Congress recognized the limitations of FDA's authority in this area and, in FDAAA, gave FDA new authorities to require safety labeling changes in certain circumstances.

Title IX, section 901 of FDAAA (Pub. L. 110-85) amended the FD&C Act by adding new section 505(o)(4) (21 U.S.C. 355(o)(4)). Section 505(o)(4) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Specifically, section 505(o)(4) of the FD&C Act applies to prescription drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application (BLA) under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application (ANDA) under section 505(j) of the FD&C Act if the NDA reference listed drug is not currently marketed. The safety labeling changes provisions in section 505(o)(4) apply to the previously listed products, including products that are not marketed, unless approval of the NDA, BLA, or ANDA has been withdrawn in the **Federal Register**. FDAAA imposes timeframes for application holders to submit and FDA staff to review safety labeling changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes.

In the **Federal Register** of April 13, 2011 (76 FR 20686), FDA announced the availability of a draft guidance for industry entitled "Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act." The notice gave interested parties the opportunity to comment by July 12, 2011. FDA carefully considered all of the comments received, and revised the guidance as appropriate. This guidance is intended to clarify how FDA will implement section 505(o)(4) of the FD&C Act, including providing a description of the types of safety labeling changes that ordinarily might be required under this section; how FDA plans to determine what

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.*

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## 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](mailto: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](mailto: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, 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