

Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: October 17, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011-27396 Filed 10-21-11; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

*Time and Dates:* 8:30 a.m.–3:15 p.m., November 15, 2011.

*Place:* Patriots Plaza I, 395 E Street, SW., Room 9000, Washington, DC 20201.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people. This meeting is available by teleconference. Please dial (877) 328-2816 and enter code 6558291.

*Purpose:* The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors shall provide guidance to the Director, National Institute for Occupational Safety and Health on research and prevention programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board shall evaluate the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards; (2) address current, relevant needs; and (3) produce intended results.

*Matters To Be Discussed:* The agenda will include the following: (1) Director Update; (2) Implementation of the National Academies Program Recommendations for Respiratory Diseases, Hearing Loss Prevention, Personal Protective Technologies, and Health Hazard Evaluations; (3) Occupational Safety and Health Workforce Needs Assessment; (4) and Future Directions for Extramural Research. Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Roger Rosa, Designated Federal Officer, BSC,

NIOSH, CDC, 395 E Street, SW., Suite 9200, Patriots Plaza Building, Washington, DC 20201, telephone (202) 245-0655, fax (202) 245-0664.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 17, 2011.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2011-27403 Filed 10-21-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0264]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** On June 28, 2011, the Agency submitted a proposed collection of information entitled "Request for Designation as Country Not Subject to the Restrictions Applicable to Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle" 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 0910-0623. The approval expires on September 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 18, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-27388 Filed 10-21-11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0424]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Temporary Marketing Permit Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Temporary Marketing Permit Applications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** On August 23, 2011, the Agency submitted a proposed collection of information entitled "Temporary Marketing Permit Applications" 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 0910-0133. The approval expires on September 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 18, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-27391 Filed 10-21-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0742]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing the registration of producers of drugs and listing of drugs in commercial distribution.

**DATES:** Submit either electronic or written comments on the collection of information by December 23, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, [juanmanuel.vilela@fda.hhs.gov](mailto:juanmanuel.vilela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—21 CFR Part 207—(OMB Control Number 0910-0045)—Extension

Requirements for drug establishment registration and drug listing are set forth in section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360) and section 351 of the Public Health Service Act, and part 207 (21 CFR part 207). Fundamental to FDA’s mission to protect the public health is the collection of this information, which is used for important activities such as postmarket surveillance for serious adverse drug reactions, inspection of drug manufacturing and processing facilities, and monitoring of drug products imported into the United States. Comprehensive, accurate, and up-to-date information is critical to conducting these activities with efficiency and effectiveness.

Under section 510 of the FD&C Act, FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510

of the FD&C Act, FDA issued part 207.<sup>1</sup> Under current § 207.20, manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premises as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute under their own label or trade name a drug product manufactured by a registered establishment are not required either to register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under current § 207.21, establishments, both domestic and foreign, must register with FDA within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually. Changes in individual ownership, corporate or partnership structure, location, or drug-handling activity must be submitted as amendments to registration under current § 207.26 within 5 days of such changes. Under § 207.20(b), private label distributors may request their own labeler code and elect to submit drug listing information to FDA. In such instances, at the time of submitting or

<sup>1</sup> This document addresses the information collection in current part 207. In the **Federal Register** of August 29, 2006 (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list, and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally also require the electronic submission of all registration and most listing information. The August 29, 2006, proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the information collection for revised part 207 will replace the information collection in this document.