

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* ANA Consultant and Evaluator Qualifications Form.

*OMB No.:* 0970-0265.

*Description:* The ANA Consultant and Evaluator Qualifications Form is used to collect information from prospective proposal reviewers in compliance with 42 USC Section 2991d-1. The form allows the Commissioner of ANA to select qualified people to review grant applications for Social and Economic Development Strategies (SEDS), Native

Language Preservation and Maintenance, and Environmental Regulatory Enhancement. The panel review process is a legislative mandate in the ANA grant funding process.

*Respondents:* Native Americans, Native Alaskans, Native Hawaiians and other Pacific Islanders.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Consultant and Evaluator Qualifications Form .....	300	1	1	300

Estimated Total Annual Burden Hours: 300

*Additional Information:*

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:*

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project,

*Fax:* 202-395-7285.

*E-mail:*

[OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV).

*Attn:* Desk Officer for the Administration for Children and Families.

Dated: November 22, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2010-29779 Filed 11-24-10; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0180]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adoption of Food and Drug Administration Food Code by Local, State and Tribal Governments**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Adoption of FDA Food Code by Local, State and Tribal Governments" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793, [Denver.Presley@FDA.HHS.GOV](mailto:Denver.Presley@FDA.HHS.GOV).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 24, 2010 (75 FR 36097), the agency announced that the proposed information collection had been submitted 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 0910-0448. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: November 19, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-29688 Filed 11-24-10; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0598]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Type A Medicated Articles**

**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 the recordkeeping requirements for manufacturers of type A medicated articles.

**DATES:** Submit either electronic or written comments on the collection of information by January 25, 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:** Johnny 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.

**Current Good Manufacturing Practice Regulations for Type A Medicated Articles—21 CFR Part 226 (OMB Control Number 0910-0154)—Extension**

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including type A medicated articles. A type A medicated article is a feed product containing a concentrated drug diluted with a feed carrier substance. A type A medicated article is intended solely for use in the manufacture of another type A medicated article or a type B or type C medicated feed. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease or for growth promotion and feed efficiency.

Statutory requirements for cGMPs for type A medicated articles have been codified in part 226 (21 CFR part 226). Type A medicated articles which are not

manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the FD&C Act. Under part 226, a manufacturer is required to establish, maintain, and retain records for type A medicated articles, including records to document procedures required under the manufacturing process to assure that proper quality control is maintained. Such records would, for example, contain information concerning receipt and inventory of drug components, batch production, laboratory assay results (*i.e.*, batch and stability testing), and product distribution.

This information is needed so that FDA can monitor drug usage and possible misformulation of type A medicated articles. The information could also prove useful to FDA in investigating product defects when a drug is recalled. In addition, FDA will use the cGMP criteria in part 226 to determine whether or not the systems used by manufacturers of type A medicated articles are adequate to assure that their medicated articles meet the requirements of the FD&C Act as to safety and also meet the article's claimed identity, strength, quality, and purity, as required by section 501(a)(2)(B) of the FD&C Act.

The respondents for type A medicated articles are pharmaceutical firms that manufacture both human and veterinary drugs, those firms that produce only veterinary drugs, and commercial feed mills.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

	No. of record-keepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
21 CFR Section:					
226.42 .....	115	260	29,900	.75	22,425
226.58 .....	115	260	29,900	1.75	52,325
226.80 .....	115	260	29,900	.75	22,425
226.102 .....	115	260	29,900	1.75	52,325
226.110 .....	115	260	29,900	.25	7,475
226.115 .....	115	10	1,150	.5	575
.....	.....	.....	.....	.....	157,550

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for record preparation and maintenance is based on Agency communications with industry. Other information needed to calculate the total burden hours (*i.e.*, manufacturing sites, number of type A medicated articles being manufactured, etc.) are derived from Agency records and experience.

Dated: November 19, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-29687 Filed 11-24-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following meeting.

*Name:* Public Meeting to release CDC's recommendations to the Department of Energy resulting from the release of the Final Report of the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project.

*Time and Date:* 5 p.m.–7 p.m., (Mountain Time), Wednesday, December 8, 2010 and 5 p.m.–7 p.m. Thursday, December 9, 2010.

*Place:* December 8, 2010, Santa Claran Hotel & Casino in Espanola (25 miles north of Santa Fe on US 84/285), 460 Riverside Drive, Espanola, New Mexico 87532, telephone 877-505-4949.

December 9, 2010, Tularosa Senior & Community Center in Tularosa (14 miles north of Alamogordo on US 70), 1050 Bookout Rd., Tularosa, New Mexico 88352, telephone 575-585-4532.

*Status:* Open to the public, limited only by the space available. The meeting room(s) accommodates approximately 100 people.

*Background:* Under a Memorandum of Understanding (MOU) signed in December 1990 with the Department of Energy (DOE) and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC.

In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between the Agency for Toxic Substances and Disease Registry (ATSDR) and DOE. The MOU delineates the responsibilities and procedures for ATSDR's

public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or a Superfund). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

*Purpose:* This study group was charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory and Trinity Site since its inception. The purpose of this meeting is to release the CDC's recommendations to the Department of Energy as a result of the release of the Final Report (<http://www.Lahdra.org>).

*Matters to Be Discussed:* Agenda items for the December 8th meeting include a presentation from the National Center for Environmental Health (NCEH) and poster sessions on various report topics. There will be time for the public to ask questions. At the December 9th meeting, ChemRisk personnel will present on the Final Report's Trinity Site chapter. All agenda items are subject to change as priorities dictate.

*Contact Person for Additional Information:* Phillip R. Green, Public Health Advisor, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, NE., (Mailstop F-58), Atlanta, Georgia 30333, telephone 770/488-3748, fax 770/488-1539, or e-mail address: [prg1@cdc.gov](mailto:prg1@cdc.gov).

Dated: November 19, 2010.

**Tanja Popovic,**

*Deputy Associate Director for Science, Centers for Disease Control and Prevention.*

[FR Doc. 2010-29778 Filed 11-24-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2010-M-0402, FDA-2010-M-0361, and FDA-2010-M-0519]

#### Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and

effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

**ADDRESSES:** Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

**FOR FURTHER INFORMATION CONTACT:** Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993-0002, 301-796-6570.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the Agency now posts this information on the Internet on FDA's home page at <http://www.fda.gov>. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available