

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]

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Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project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CDC's recommendations to the Department of Energy resulting from the release of the Final Report of the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project.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

Dated: November 19, 2010.

Tanja Popovic,

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

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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