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Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project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CDC's recommendations to the Department of Energy resulting from the release of the Final Report of the Los Alamos Historical Document Retrieval and Assessment (LAHDRA)Project.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

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

safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2010, through September 30, 2010. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2010, THROUGH SEPTEMBER 30, 2010

PMA No. Docket No.	Applicant	Trade name	Approval date
P080027, FDA–2010–M–0402	OraSure Technologies, Inc	ORAQUICK HCV RAPID ANTIBODY TEST.	June 25, 2010.
P050034, FDA–2010–M–0361	Vision Care Ophthalmic Technologies, Ltd.	IMPLANTABLE MINIATURE TELESCOPE.	July 1, 2010.
P080026, FDA–2010–M–0519	Abbott Molecular, Inc	ABBOTT REALTIME HBV ASSAY	August 13, 2010.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: November 18, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–29731 Filed 11–24–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3229–N]

Medicare Program; Quality Improvement Organization (QIO) Contracts: Solicitation of Proposals From In-State QIOs—Idaho, Maine, South Carolina, and Vermont

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice fulfills the Secretary's obligation under section 1153(i) of the Social Security Act (the Act) to provide at least 6 months' advance notice of the expiration dates of contracts with out-of-State Quality Improvement Organizations (QIOs) before renewing any of those QIOs' contracts. It also specifies the period of time in which in-State QIOs may submit a proposal for those contracts.

DATES: Interested organizations may submit a proposal to perform the QIO work in any of the States listed in this announcement. The request for proposal (RFP) will be made available to all interested organizations through the Federal Business Opportunities (*http://www.fedbizopps.gov*) Web site. CMS anticipates that the RFP for the QIO contracts will be released sometime during the month of February 2011. Interested organizations should monitor the Federal Business Opportunities Web site for all information relating to the RFP.

ADDRESSES: Proposals for the contracts must be submitted to the Centers for Medicare & Medicaid Services, Acquisitions and Grants Groups, OAGM, Attn.: Naomi Haney-Ceresa, 7500 Security Boulevard, Mail Stop C2–21–15, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Alfreda Staton, (410) 786–4194.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (title I, subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248) amended Part B of title XI of the Act (the Act) by establishing the Utilization and Quality Control Peer Review Organization program.

Utilization and Quality Control Peer Review Organizations, now known as Quality Improvement Organizations (QIOs), currently review certain health care services furnished under title XVIII of the Social Security Act (the Act) (Medicare) to determine whether those services are reasonable, medically necessary, provided in the appropriate setting, and are of a quality that meets professionally recognized standards. QIO activities are a part of the Health Care Quality Improvement Program (HCQIP), a program that supports our mission to ensure health care quality for our beneficiaries. The HCQIP rests on the belief that a plan's, provider's, or practitioner's own internal quality management system is key to good performance. The HCQIP is carried out locally by the QIO in each State. Under the HCQIP, QIOs provide critical tools (for example, quality indicators and information) for plans, providers, and practitioners to improve the quality of care provided to Medicare beneficiaries. The Congress created the QIO program in part to redirect, simplify, and enhance the cost-effectiveness and efficiency of the peer review process.

In June 1984, we began awarding contracts to QIOs. We currently maintain 53 QIO contracts with organizations that provide medical review activities for the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. The organizations that are eligible to contract as QIOs have satisfactorily demonstrated that they are either physician-sponsored or physician-access organizations in accordance with section 1152 of the Act and our regulations at 42 CFR 475.102 and 475.103. A physician-sponsored organization is one that is both composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the respective review area and who are representative of the physicians practicing in the review area. A physician-access organization is one that has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to ensure adequate peer review of the services furnished by the various medical specialties and subspecialties. In addition, a QIO cannot be a health care facility, health care facility association, a health care facility affiliate, or in most cases a payor organization. (The regulations provide that, in the event CMS determines no otherwise qualified non-payor organization is available to undertake a given QIO contract, CMS may select a payor organization which otherwise meets certain requirements to be eligible to conduct Utilization and Quality Control Peer Review as specified in Part B of Title XI of the Act and its implementing regulations.) Section 1152(2) of the Act requires QIOs to perform review functions in an