http://www.hhs.gov/healthit/ahic/healthrecords/ehr_instruct.html.

Dated: September 7, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–4506 Filed 9–12–07; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Personalized Healthcare Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the ninth meeting of the American Health Information Community Personalized Healthcare Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.)

DATES: October 25, 2007, from 2 p.m. to 5 p.m. [Eastern Time].

ADDRESSES: Mary C. Switzer Building (330 C. Street, SW., Washington, DC 20201), Conference Room 4090. Please bring photo ID for entry to a Federal building.

FOR FURTHER INFORMATION CONTACT: *http://www.hhs.gov/healthit/ahic/healthcare/.*

SUPPLEMENTARY INFORMATION: The Workgroup will discuss possible common data standards to incorporate interoperable, clinically useful genetic/genomic information and analytical tools into Electronic Health Records (EHR) to support clinical decision-making for the clinician and consumer.

The meeting will be available via Web cast. For additional information, go to: *http://www.hhs.gov/healthit/ahic/healthcare/phc_instruct.html.*

Dated: September 7, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–4507 Filed 9–12–07; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS).

Time and Date:

September 25, 2007, 9 a.m.–4 p.m.

September 26, 2007, 10 a.m.–2:45 p.m.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814, Phone: (301) 897–9400.

Status: Open.

Purpose: At this meeting the Committee will hear presentations and hold discussions on several health data policy topics. On the morning of the first day the Committee will hear updates from the Department, the Centers for Medicare and Medicaid Services, and the Office of the National Coordinator. They will also hear updates and status reports from Subcommittees and hold a discussion on secondary uses of health records data. This discussion will be continued in the afternoon and the Committee will hear an update from the Quality Workgroup.

On the morning of the second day the Committee will review its 2005–2006 report to Congress and take action on other products as needed. In the afternoon there will be a continuation of the discussion on secondary uses of health record data and the remainder of the time will be spent on Committee administrative operations.

The times shown above are for the full Committee meeting. Subcommittee breakout sessions are scheduled for late in the afternoon of the first day and in the morning prior to the full Committee meeting on the second day. Agendas for these breakout sessions will be posted on the NCVHS Web site (URL below) when available.

Contact Person for More Information: Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458–4245. Information also is available on the NCVHS home page of the HHS Web site: *http://www.ncvhs.hhs.gov/,* where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458–4EEO (4336) as soon as possible.

Dated: September 5, 2007.

James Scanlon,

Deputy Assistant Secretary for Planning and Evaluation (SDP), Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 07–4508 Filed 9–12–07; 8:45 am]

BILLING CODE 4151–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2007M–0174, 2007M–0259, 2007M–0161, 2007M–0160, 2007M–0151, 2007M–0152, 2007M–0153, 2007M–0188, 2007M–0156, 2007M–0154, 2007M–0180, 2007M–0189, 2007M–0190, 2007M–0253, 2007M–0255, 2007M–0254]

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: Samie Allen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013.

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 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 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 April 1, 2007, through June 30, 2007. 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 APRIL 1, 2007, THROUGH JUNE 30, 2007.

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P050049/2007M–0174	Abbott Laboratories	ABBOTT AXSYM HBSAG ASSAY	June 1, 2006
P040048/2007M–0259	Zimmer, Inc.	TRILOGY AB ACETBULAR SYSTEM	June 28, 2006
P060003/2007M–0161	Abbott Laboratories	AXSYM AUSAB REAGENT PACK, STANDARD CALIBRATORS, CONTROLS	August 7, 2006
P060009/2007M–0160	Abbott Laboratories	AXSYM CORE-M 2.0 & 2.0 CONTROLS	August 25, 2006
P050048/2007M–0151	Bio-Rad Laboratories, Inc.	MONOLISA ANTI-HBS EIA	August 25, 2006
P060007/2007M–0152	Abbott Laboratories	ARCHITECT HBSAG REAGENT KIT, CALIBRATORS, CONTROLS, CONFIRMATORY REAGENT KIT, CONFIRMATORY MANUAL DILUENT	September 7, 2006
P060012/2007M–0153	Abbott Laboratories	AXSYM CORE 2.0 & AXSYM CORE 2.0 CONTROLS	September 8, 2006
P990037(S24)/2007M–0188	Vascular Solutions, Inc.	VASCULAR SOLUTIONS D-STAT FLOWABLE HEMOSTAT	December 22, 2006
H060003/2007M–0156	EV3 Neurovascular	ONYX LIQUID EMBOLIC SYSTEM (ONYX HD–500, MODEL 105–8101–500)	April 11, 2007
P050046/2007M–0154	Guidant Corp.	ACUITY STEERABLE LEAD MODELS 4554, 4555, & 4556	April 13, 2007
P040024(S006)/2007M–0180	Medicis Aesthetics Holdings, Inc.	PERLANE INJECTABLE GEL	May 2, 2007
P060011/2007M–0189	Rayner Surgical, Inc.	C-FLEX MODEL 570C INTRAOCULAR LENS (IOL)	May 3, 2007
H060001/2007M–0190	Cordis Neurovascular, Inc.	ENTERPRISE VASCULAR RECONSTRUCTION DEVICE AND DELIVERY SYSTEM	May 8, 2007
P050004/2007M–0253	Electro Medical Systems (EMS) S.A.	EMS SWISS DOLORCLAST	May 8, 2007
P050012(S001)/2007M–0255	Dexcom, Inc.	STS–7 CONTINUOUS GLUCOSE MONITORING SYSTEM	May 31, 2007
P060034/2007M–0254	Bio-Rad Laboratories	BIO RAD MONOLISA ANTI-HBC IGM EIA	May 31, 2007

II. Electronic Access

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

Dated: August 30, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–18034 Filed 9–12–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

U.S Customs and Border Protection

Agency Information Collection Activities: U.S-Jordan Free Trade Agreement

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: U.S.-Jordan Free Trade Agreement. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (72 FR 38092) on July 12, 2007, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before October 15, 2007.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Nathan Lesser, Desk Officer, Department of Homeland Security/Customs and Border Protection, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: U.S.-Jordan Free Trade Agreement.

OMB Number: 1651–0128.

Form Number: None.

Abstract: The U.S.-Jordan Free Trade Agreement was established to reduce and eliminate barriers, strengthen and develop economic relations, and to lay the foundations for further cooperation by reduced duty-treatment on imported goods.

Current Actions: There are no changes to the information collection. This submission is being submitted to extend the expiration date.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 2,500.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 500.

Estimated Total Annualized Cost on the Public: N/A.

If additional information is required contact: Tracey Denning, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Dated: September 6, 2007.

Tracey Denning,

Agency Clearance Officer, Information Services Branch.

[FR Doc. E7–18001 Filed 9–12–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S Customs and Border Protection

Agency Information Collection Activities: Haitian Hemispheric Opportunity Through Partnership Encouragement Act of 2006

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Proposed collection; comments requested.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Haitian Hemispheric Opportunity Through Partnership Encouragement (''HOPE'') Act of 2006. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** (72 FR 38092) on July 12, 2007, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.

DATES: Written comments should be received on or before October 15, 2007.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Nathan Lesser, Desk Officer, Department of Homeland Security/Customs and Border Protection, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: U.S. Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Your comments should address one of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the