

Dated: March 7, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. 2006M-0384, 2006M-0385, 2006M-0386]

#### Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data 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 by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability through the Internet and the FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

**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 include the appropriate docket number as listed in tables 1 and 2 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

#### FOR FURTHER INFORMATION CONTACT:

Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

#### 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**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. 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 administrative 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 following is a list of PMAs approved by CBER for which summaries of safety and effectiveness data were placed on the Internet from March 1, 2006, through June 30, 2006, and from July 1, 2006, through September 30, 2006. There were no denial actions during either 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 SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE MARCH 1, 2006, THROUGH JUNE 30, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP050009/0/2006M-0384	Chembio Diagnostic Systems, Inc.	SURE CHECK HIV 1/2 ASSAY	May 25, 2006
BP050010/0/2006M-0385	Chembio Diagnostic Systems, Inc.	HIV 1/2 STAT-PAKT ASSAY	May 25, 2006

TABLE 2.—LIST SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2006, THROUGH SEPTEMBER 30, 2006

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP050030/0/2006M-0386	Bayer Healthcare LLC	ADVIA Centaur HIV 1/0/2 Enhanced Assay	May 18, 2006

## II. Electronic Access

Persons with access to the Internet may obtain the documents at <http://www.fda.gov/cber/products.htm>.

Dated: March 5, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### National Communications System

[Docket No. NCS-2007-0001]

#### National Security Telecommunications Advisory Committee

**AGENCY:** National Communications System, DHS.

**ACTION:** Notice of partially closed advisory committee meeting.

**SUMMARY:** The President's National Security Telecommunications Advisory Committee (NSTAC) will be meeting by teleconference; the meeting will be partially closed.

**DATES:** Thursday, March 29, 2007, from 2 p.m. until 3 p.m.

**ADDRESSES:** The meeting will take place by teleconference. For access to the conference bridge and meeting materials, contact Mr. Kelvin Coleman at (703) 235-5643 or by e-mail at [kelvin.coleman@dhs.gov](mailto:kelvin.coleman@dhs.gov) by 5 p.m. on Friday, March 23, 2007. If you desire to submit comments, they must be submitted by April 5, 2007. Comments must be identified by NCS-2007-0001 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [NSTAC1@dhs.gov](mailto:NSTAC1@dhs.gov). Include docket number in the subject line of the message.

- *Mail:* Office of the Manager, National Communications System (N5), Department of Homeland Security, Washington, DC, 20529.

- *Fax:* 1-866-466-5370.

*Instructions:* All submissions received must include the words "Department of Homeland Security" and NCS-2007-0001, the docket number for this action. Comments received will be posted without alteration at [www.regulations.gov](http://www.regulations.gov), including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received by the NSTAC, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Ms. Kiesha Gebreyes, Chief, Industry Operations Branch at (703) 235-5525, e-mail: [Kiesha.Gebreyes@dhs.gov](mailto:Kiesha.Gebreyes@dhs.gov) or write the Deputy Manager, National Communications System, Department of Homeland Security, IP/NCS/N5.

**SUPPLEMENTARY INFORMATION:** The NSTAC advises the President on issues and problems related to implementing national security and emergency preparedness telecommunications policy. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.1 *et seq.*).

At the upcoming meeting, between 2 p.m. and 2:25 p.m., the members will receive comments from government stakeholders and receive an update from the NSTAC's International Task Force (ITF). This portion of the meeting will be open to the public.

Between 2:25 p.m. and 3 p.m., the committee will discuss Global Infrastructure Resiliency (GIR). This portion of the meeting will be closed to the public.

Persons with disabilities who require special assistance should indicate this when arranging access to the teleconference and are encouraged to identify anticipated special needs as early as possible.

*Basis for Closure:* The GIR discussion will likely involve sensitive infrastructure information concerning system threats and explicit physical/cyber vulnerabilities of the undersea communications infrastructure. Public disclosure of such information would heighten awareness of potential vulnerabilities and increase the likelihood of exploitation by terrorists or other motivated adversaries. Pursuant to Section 10(d) of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App. 1 *et seq.*), the Department has determined that this discussion will concern matters which, if disclosed, would be likely to frustrate significantly the implementation of a proposed agency action. Accordingly, the relevant portion of this meeting will be closed to the public pursuant to the authority set forth in 5 U.S.C. 552b(c)(9)(B).

**Sallie McDonald,**

*Deputy Manager, National Communications System.*

[FR Doc. 07-1217 Filed 3-12-07; 2:43 pm]

**BILLING CODE 4410-10-P**

## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

#### Proposed Collection; Comment Request Regulations Relating to Recordation and Enforcement of Trademarks and Copyrights

**ACTION:** Notice and request for comments.

**SUMMARY:** As part of its continuing effort to reduce paperwork and respondent burden, Bureau of Customs and Border Protection (CBP) invites the general public and other Federal agencies to comment on an information collection requirement concerning the Regulations Relating to Recordation and Enforcement of Trademarks and Copyrights (Part 133 of the CBP Regulations). This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)).

**DATES:** Written comments should be received on or before May 14, 2007, to be assured of consideration.

**ADDRESSES:** Direct all written comments to Bureau of Customs and Border Protection, Information Services Group, Attn.: Tracey Denning, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information should be directed to Bureau of Customs and Border Protection, Attn.: Tracey Denning, 1300 Pennsylvania Avenue NW., Room 3.2.C, Washington, DC 20229, Tel. (202) 344-1429.

**SUPPLEMENTARY INFORMATION:** CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3505(c)(2)). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) estimates of capital or start-up costs and costs of operations, maintenance, and purchase of services to provide information. The comments that are submitted will be summarized and included in the CBP request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

*Title:* Regulations Relating to Recordation and Enforcement of Trademarks and Copyrights (Part 133 of the CBP Regulations).

*OMB Number:* 1651-0123.

*Form Number:* None.

*Abstract:* Trademark and trade name owners and those claiming copyright protection must provide information sufficient to enable CBP officers to identify violative articles at the borders.

*Current Actions:* This submission is being submitted to extend the expiration date.

*Type of Review:* Extension (without change to the burden hours).

*Affected Public:* Businesses, Individuals.

*Estimated Number of Respondents:* 2,000.

*Estimated Time per Respondent:* 2 hours.

*Estimated Total Annual Burden Hours:* 4,000.

*Estimated Total Annualized Cost on the Public:* \$380,000.