DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board: Notification of Public Teleconference

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Biodefense Science Board (NBSB) will hold a teleconference meeting. The meeting is open to the public. Pre-registration is NOT required, however, individuals who wish to participate in the public comment session should e-mail NBSB@HHS.GOV to RSVP.

DATES: The meeting will be held on February 10, 2010 from 2 p.m. to 4 p.m. ET.

ADDRESSES: The meeting will occur by conference call to facilitate attendance. To attend, call 1–866–395–4129, pass-code “ASPR.” Please call 15 minutes prior to the beginning of the conference call to facilitate attendance.

FOR FURTHER INFORMATION: E-mail: NBSB@HHS.GOV

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d–7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary on other matters related to public health emergency preparedness and response.

The Board will discuss and consider recommendations from the National Biodefense Science Board’s Medical Countermeasure Markets and Sustainability Working Group report titled “Inventory of Issues Constraining or Enabling Industry Involvement in Medical Countermeasure Efforts.” Members of the public are invited to attend by teleconference via a toll-free call-in phone number. The teleconference will be operator assisted to allow the public the opportunity to provide comments to the Board. Public participation will be limited to time and space available. Public comments will be limited to no more than 3 minutes per speaker. To be placed on the public comment list, notify the operator when you join the teleconference.

Public comments received by close of business one week prior to each teleconference will be distributed to the NBSB in advance. Submit comments via e-mail to NBSB@HHS.GOV, with “NBSB Public Comment” as the subject line. A draft agenda and any additional materials/agendas will be posted on the NBSB Web site (http://www.hhs.gov/aspr/omsph/nbsb/) prior to the meeting.


Nicole Lurie,
Assistant Secretary for Preparedness and Response.

[FR Doc. 2010–778 Filed 1–15–10; 8:45 am]
BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2009.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Teresa L. Hays, Committee Management Officer, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app. 1) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2008, through September 30, 2009:

Center for Biologics Evaluation and Research:

Blood Products Advisory Committee,
Vaccines and Related Biological Products Advisory Committee, Center for Drug Evaluation and Research:
Anesthetic and Life Support Drugs Advisory Committee,
Antiviral Drugs Advisory Committee,
Endocrinologic and Metabolic Drugs Advisory Committee, Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of report for Circulatory System Devices Panel).
Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:
2. The Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–807 Filed 1–15–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA–2009–N–0488]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs; Adverse Event Reports on Forms FDA 1932, 1932a, and 2301

OMB Control No. 0910–0284—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(b)(1) and § 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see § 514.80(b)).

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may not be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

Under § 514.80(d), an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, “Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.” Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, “Transmittal of Periodic Reports and Promotional Material for New Animal Drugs” (see § 514.80(d)). Form FDA 1932a, “Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report” allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

The electronic versions of Forms FDA 1932 and 1932a have been incorporated into the agency-wide information collection (MedWatchPlusPortal and Rational Questionnaire) that was announced for public comment in the Federal Register on October 23, 2008 (73 FR 63153). MedWatchPlus Portal and Rational Questionnaire is part of a new electronic system for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products. In the Federal Register of May 20, 2009 (74 FR 23721), FDA announced the submission for OMB review and clearance of the electronic data collection using MedWatchPlus Portal and Rational Questionnaire.

Burden hours for the electronic versions of these forms were included as part of the MedWatchPlus Portal and Rational Questionnaire information collection approved under OMB control number 0910–0645. It is estimated that, during the first 3 years that the MedWatchPlus Portal is in use, half of the reports will be submitted in paper format and half will be submitted electronically. In order to avoid double counting, an estimated 50 percent of total annual responses for FDA Form 1932 (404) and FDA Form 1932a (81.5) are counted here as part of OMB Control No. 0910–0284 for the paper versions of Forms FDA 1932 and 1932a, and an estimated 50 percent of the total annual responses (404) and (81.5) for Form FDA 1932 and FDA Form 1932a respectively, are counted as part of OMB Control No. 0910–0645 for the electronic reporting of these adverse reports using the MedWatchPlus Portal.

In the Federal Register of October 15, 2009 (74 FR 52967), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

In a separate 30-day notice, FDA requested public comment on data elements associated with revisions to Forms FDA 1932 and 1932a (both paper and electronic) under revised OMB Control No. 0910–0645 (November 20, 2009, 74 FR 60265). The agency plans to give companies time to accommodate the revisions since the proposed revisions may require changes to validated databases. The agency plans to provide a transition period for respondents until September 30, 2010, during which the current FDA Form 1932 (version dated 01/2007—approved under this OMB Control No. 0910–0284) will be accepted as well as the revised FDA Form 1932 approved under revised OMB Control No. 0910–0645. After the transition period, Form FDA 2301 will