FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 66 FR 54527, October 29, 2001.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:30 a.m. Wednesday, October 31, 2001.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting: Consideration of quorum and other voting requirements for Board action.

CONTACT PERSON FOR MORE INFORMATION: Michelle A. Smith, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 31, 2001.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 01–27763 Filed 10–31–01; 4:41 pm]

BILLING CODE 6210–01–P

GENERAL ACCOUNTING OFFICE

Advisory Council on Government Auditing Standards; Notice of Meeting

The Advisory Council on Government Auditing Standards will meet Monday, November 19, 2001 from 8:30 a.m. to 5:00 p.m., in room 7C13 of the General Accounting Office building, 441 G Street, NW., Washington, DC.

The Advisory Council on Government Auditing Standards will hold a meeting to discuss issues that may impact government auditing standards. The meeting is open to the public. Any interested person who plans to attend the meeting as an observer should present a copy of this meeting notice and a form of picture identification to the GAO Security Desk on the day of the meeting to obtain access to the GAO Building. Council discussions and reviews are open to the public. Members of the public will be provided an opportunity to address the Council with a brief (five minute) presentation on Monday afternoon.

For further information or to notify the Council you plan to attend the meeting, please contact Jennifer Allison, Council Assistant, 202–512–3423. Please check the Government Auditing Standards web page (*www.gao.gov/govaud/ybk01.htm*) one week prior to the meeting for a final agenda.

Marcia B. Buchanan,

Assistant Director.

[FR Doc. 01–27664 Filed 11–2–01; 8:45 am]

BILLING CODE 1610–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0222]

Agency Information Collection Activities; Announcement of OMB Approval; Third-Party Review Under FDAMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Third-Party Review Under FDAMA'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 27, 2001 (66 FR 45047), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0375. The approval expires on October 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at

http://www.fda.gov/ohrms/dockets.

Dated: October 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–27642 Filed 11–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0231]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by December 5, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report—21 CFR Part 510 (OMB Control No. 0910–0012)—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 360b(l)) and 21 CFR 510.300, 510.301, and 510.302 require that applicants of approved new animal drug applications (NADAs) submit within 15 working days of receipt, complete records of reports of certain adverse drug reactions and unusual failure of new animal drugs. Other reporting requirements of adverse reactions to these drugs must be reported annually or semiannually in a specific format. This continuous monitoring of approved new animal drugs, affords the primary means by which FDA obtains information regarding potential problems in safety and effectiveness of

marketed animal drugs and potential manufacturing problems. Data already on file with FDA is not adequate because animal drug effects can change over time and less apparent effects may take years to manifest themselves. Reports are reviewed along with those previously submitted for a particular drug to determine if any change is needed in the product or labeling, such as package insert changes, dosage changes, additional warnings or contraindications, or product reformulation.

Adverse reaction reports are required to be submitted by the drug manufacturer on FDA Forms 1932 or 1932a (voluntary reporting form), following complaints from animal owners or veterinarians. Likewise, product defects and lack of effectiveness complaints are submitted to FDA by the drug manufacturer following their own detection of a problem or complaints from product users or their veterinarians using FDA Forms 1932 and 1932a . FDA Form 2301 is available for the required transmittal of periodic reports and promotional material for new animal drugs. Respondents to this collection of information are applicants of approved NADAs.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Form FDA 2301 ...	510.302(a)	190	13.16	2,500	0.5	1,250
Form FDA 1932 ...	510.302(b)	190	94.74	18,000	1.0	18,000
Form FDA 1932a (voluntary)	510.302(b)	100	1.0	100	1.0	100
Total burden hours						19,350

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Response per Recordkeeper	Hours per Recordkeeper	Total Hours
510.300(a) and 510.301(a)	190	13.16	2,500	10.35	25,875
510.300(b) and 510.301(b)	190	94.74	18,000	0.50	9,000
Total burden hours					34,875

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry. Other information needed to calculate the total burden hours (i.e., adverse drug reaction, lack of effectiveness, and product defect reports) are derived from agency records and experience.

Dated: October 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–27641 Filed 11–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0489]

Draft FDA Guidance on the Establishment and Operation of Clinical Trial Data Monitoring Committees; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH), is announcing the following public meeting: Draft FDA Guidance on the Establishment and Operation of Clinical Trial Data Monitoring Committees (DMCs). The topics to be discussed are addressed in the draft entitled ''Guidance for Clinical Trial Sponsors On the Establishment and Operation of Data Monitoring Committee.'' These topics include: The history of DMCs, the types of clinical trials in which DMCs are most important, DMC membership and operations, independence of DMCs, and the regulatory requirements relevant to DMCs.

Date and Time: The meeting will be held on November 27, 2001, from 9 a.m. to 5 p.m.

Location: The meeting will be held at The Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact: Melanie Whelan, Center for Biologics Evaluation and Research (HFM–40), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3841, FAX 301–827–3843, or e-mail: Whelan@cber.fda.gov.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), to Melanie Whelan (address above) by November 20, 2001. We encourage early registration because seating is limited. There is no registration fee.

If you need special accommodations due to a disability, please contact Melanie Whelan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This meeting will provide a forum for all members of the public to express their opinions and suggestions on the draft entitled ''Guidance for Clinical Trial Sponsors On the Establishment and Operation of Data Monitoring Committees.'' The draft guidance is intended to address scientific, ethical, and practical issues related to the establishment and operation of DMCs for clinical trials. The meeting will be of primary interest to sponsors of clinical trials evaluating FDA-regulated products. The objectives of the meeting are to: (1) Present the material in the draft guidance document and (2) solicit