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:

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and

2. The Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: January 13, 2010.

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by February 18, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0284. Also include the FDA docket number found in brackets in the heading of this document

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr. Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Records and Reports Concerning Experience With Approved New Animal Drugs; Adverse Event Reports on Forms FDA 1932, 1932a, and 2301 (OMB Control Number 0910–0284)—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(l) 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 (MedWatch^{Plus}Portal and Rational Questionnaire) that was announced for public comment in the **Federal Register** on October 23, 2008 (73 FR 63153). MedWatch^{Plus} 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 MedWatch^{Plus} Portal and Rational Questionnaire.

Burden hours for the electronic versions of these forms were included as part of the MedWatch^{Plus} Portal and Rationale Questionnaire information collection approved under OMB control number 0910–0645. It is estimated that, during the first 3 years that the MedWatch^{Plus} 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 MedWatch^{Plus} 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

continue to be counted as part of OMB Control No. 0910–0284.

The reporting and recordkeeping burden estimates, including the total number of annual responses, are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The annual frequency of responses was calculated as the total annual responses divided by the number of respondents.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section or Section of the Act	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3)	1932[2]	404	44.26	17,881	1	17,881
Voluntary reporting FDA Form 1932a for the public	1932a[2]	81.5	1	81.5	1[3]	81.5
514.80(b)(4)	2301	84	17.0	1,428	16	22,848
514.80(b)(5)(i)	2301	84	0.31	26	2	52
514.80(b)(5)(ii)	2301	84	33.92	2,849	2	5,698
514.80(b)(5)(iii)	2301	646	0.08	51.68	2	103
Total hours						46,663.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden hours were determined as explained previously.
[3] The hours per response for paper versions of Forms FDA 1932 and 1932a are assumed to be 1 hour. The hours per response for the electronic version of Form FDA 1932 is assumed to be 1 hour, while the electronic version of Form FDA 1932a is assumed to take .6 hours to complete the form and gather the required information as part of the MedWatch[Plus] Portal information collection (see 74 FR 23721 at 23727).

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
514.80(e)[2]	646	7.20	4,651	14	65,116.8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Section 514.80(e) covers all recordkeeping hours for all adverse event reporting.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–782 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–0483]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet—Form FDA 3601

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by February 18, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0511. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Medical Device User Fee Cover Sheet—Form FDA 3601—OMB Control Number 0910–0511—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the "Medical Device User Fee Cover Sheet," is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees