Dated: October 7, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–24825 Filed 10–14–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0488]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for recordkeeping and reports concerning experience with approved new animal drugs. The information contained in the reports required by the regulation enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy.

DATES: Submit written or electronic comments on the collection of information by December 14, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Records and Reports Concerning Experience With Approved New Animal Drugs; Adverse Event Reports on Forms FDA 1932, 1932a, and 2301—21 CFR Section 514.80 (OMB No. 0910–0284)—Extension

Sections 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. Postapproval 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** of 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 number 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 number 0910–0645 for the electronic reporting of these adverse reports using the MedWatch^{Plus} Portal.

The paper versions of Forms FDA 1932 and 1932a, as well as Form FDA

2301, will continue to be counted as part of OMB control number 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	17,882.5	1	17,882.5
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	49	2	98
Total Hours						46,660

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden hours were determined as explained above.
[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, May 20, 2009).

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	4651	14	65,116.8
Total					1,541

[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: October 7, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Health Disparities Subcommittee, Advisory Committee to the Director (ACD), Centers for Disease Control (CDC); Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned subcommittee.

Time and Date: 2 p.m.–4:30 p.m., October 28, 2009.

Place: The meeting will be convened at the CDC, 1600 Clifton Road, NE., Atlanta, GA 30333, Building 19, Auditorium B1, Global Communications Center. Please see *Supplementary Information* for details on accessing the meeting location.

Status: Open to the public, limited only by the availability of space. The meeting room accommodates approximately 90 people.

Purpose: The Subcommittee will provide advice to the CDC Director through the Advisory Committee to the Director on strategic and other broad issues facing CDC.

Matters To Be Discussed: ACD Health Disparities Subcommittee 2009 Action Agenda; CDC Director's Health Disparity Indicator Project Update, Director's Priorities and Reorganization/Structure.

Agenda items are subject to change as priorities dictate.

Supplementary Information: To participate in the meeting, please plan to register with CDC Security Officials at the Visitor's Center at least one hour prior to the meeting. A government-issued picture ID will be required. All persons who do not have a CDC/Health and Human Services identification will have to be escorted to the meeting.

Contact Person for More Information: Walter W. Williams, M.D., M.P.H., Designated Federal Officer, Health Disparities Subcommittee, ACD, CDC, 1600 Clifton Road, NE., M/S E–67, Atlanta, Georgia 30333. Telephone 404/498–2310, E-mail: *http://www1@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 8, 2009.

Andre Tyler,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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