and other entities as part of the settlement of Federal health care program fraud investigations arising under civil and administrative false claims statutes. These obligations are set forth in a CIA. A provider or an entity consents to a CIA in conjunction with a civil or administrative settlement and in exchange for OIG's agreement not to seek to exclude that health care provider or entity from participation in Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. 1320a–7. False claims submitted in violation of the False Claims Act or Civil Monetary Penalties Law give rise to OIG's permissive exclusion authority under 42 U.S.C. 1320a–7(b)(7).

The typical term of a CIA is 5 years. CIAs seek to ensure the integrity of Federal health care program claims submitted by the provider. CIAs generally include requirements to, among other things: (1) Hire a compliance officer; (2) appoint a compliance committee; (3) develop written standards and policies; (4) implement a comprehensive employee training program; (5) establish a confidential disclosure program; (6) restrict employment of ineligible persons; (7) report overpayments, reportable events, and ongoing investigations/legal proceedings; and (8) provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.

When resolving cases that involve quality-of-care allegations, OIG often requires health care providers to enter into quality-of-care CIAs. OIG may enter into quality-of-care CIAs with many different types of health care providers, including, but not limited to, skilled nursing facilities, assisted-living facilities, psychiatric facilities, intermediate care facilities for the mentally retarded, hospitals, physician practices, dental practices, and management companies. Under these quality-of-care CIAs, health care providers agree to compliance obligations that include quality assurance and improvement. One such obligation is to retain an appropriately qualified monitor, which is appointed by OIG after consultation with the health care provider. The monitor selected contracts directly with the provider. The monitor does not enter into any contractual relationship with OIG or act as an agent for OIG.

The monitor typically is responsible for assessing the effectiveness, reliability, and thoroughness of the provider's: (1) Internal quality control systems; (2) response to quality-of-care issues; (3) development and implementation of corrective action plans and the timeliness of such actions; (4) proactive steps to ensure that each patient receives care in accordance with basic care, treatment, and protection-from-harm standards; the governing regulations; and the policies and procedures required to be adopted under the CIA; and (5) in residential settings, compliance with staffing requirements. In making these assessments, the monitor conducts site visits, analyzes available data, observes facility and corporate-level committee meetings, and reviews relevant documents. The monitor submits regular written reports to the provider and OIG.

Responses to This Notice

OIG is interested in hearing from organizations that believe they have the capability to be a monitor for quality-of-care CIAs. Please include in any response to this notice the following:

1. The name of the organization;
2. The size and location(s) of the organization;
3. The qualifications of the organization to serve as a monitor for quality-of-care CIAs;
4. The organization's capacity to monitor large providers with locations in multiple States;
5. The organization's clinical experience and expertise;
6. The organization's experience with quality assessment, assurance, and improvement;
7. The organization's prior monitoring experience, including, but not limited to, systems reviews and auditing; and
8. An indication of whether the organization has any current or prior (within the last 5 years) Federal Government contracts or is on any General Services Administration or HHS list of approved contractors.

OIG will review each response submitted to this notice to assess whether the organization may be appropriate to serve as a monitor for quality-of-care CIAs. The assessment will not be for the purpose of making any definitive determination regarding whether a particular organization is qualified to be a monitor or creating a list of pre-approved monitors. Factors that OIG considers when assessing whether an organization may be an appropriate monitor for a particular CIA include, among other things, the organization's clinical expertise, capacity to handle a particular monitoring relationship, quality monitoring experience, geographic location, and independence and objectivity. Each provider and quality-of-care CIA is unique. Accordingly, the selection of an appropriate monitor for any given quality-of-care CIA requires consideration of unique and individualized factors. In order to select an appropriate monitor for any individual quality-of-care CIA, OIG may contact an organization that submitted information in response to this notice to request additional information. In selecting a monitor, OIG will not be limited to organizations that submitted information in response to this notice.

Any organization submitting information in response to this notice should identify any information that it believes is trade secret, or commercial or financial information, and privileged or confidential under exemption four of the Freedom of Information Act (FOIA). Consistent with the HHS FOIA regulations, set forth in 45 CFR Part 5, when OIG receives a request for such records and OIG determines that OIG may be required to disclose them, OIG will make reasonable efforts to notify the organization about these facts.

Daniel R. Levinson,

Inspector General.

[FR Doc. E9–24715 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–0483]

Agency Information Collection Activities; Proposed Collection; 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 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 Form FDA 3601 entitled ''Medical Device User Fee Cover Sheet,'' which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

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.

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

The Federal Food, Drug, and Cosmetic Act (the 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 submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications.

The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal year (FY) 2008. CDRH received approximately 5,095 annual responses that included the following submissions: 16 premarket approval applications (PMA) (PMA, PDP, PMR, BLA),[1] 3,625 premarket notifications, 8 modular premarket applications, 9 panel track supplements, 201 real-time supplements, 173 one hundred eighty-day supplements, 633 thirty-day notices, ninety-three 513(g) requests, and 337 annual fees for periodic reporting.

CBER received approximately 97 annual responses that included the following submissions: 2 premarket approval applications (PMA, PDP, PMR, BLA), 1 BLA efficacy supplement, 50 premarket notifications, 3 one hundred eighty-day supplements, 2 real-time supplements, 20 thirty-day notices, 3hree 513(g) requests, and 16 annual fees for periodic reporting.

The number of received annual responses in FY 2008 included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3601	5,192	1	5,192	.30	1,557.6
Total Hours					1,557.6

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

[1] PDP means product development protocol; PMR means postmarketing requirements; and BLA means biologics license applications.

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