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

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 (PMAs) (PDP, PMR, and BLA),[1] 3,625 premarket notifications, 8 modular premarket applications, 9 panel track supplements, 201 real-time supplements, 173 180-day supplements, 633 30-day notices, 93 513(g) requests, and 337 annual fees for periodic reporting.

CBER received approximately 97 annual responses that included the following submissions: 2 PMAs, 1 BLA efficacy supplement, 50 premarket notifications, 3 180-day supplements, 2 real-time supplements, 20 30-day notices, 3 513(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]

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Medical Device Manufacturers	3601	5,192	1	5,192	18/60	1,558

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

In the **Federal Register** of October 15, 2009 (74 FR 52965), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–790 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–0465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions

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 0910–0546. 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.

Food Additive Petitions (OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the act specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but seek to explain the requirements and provide a standard format for submission of petitions, that when implemented, will speed up the time for processing. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 573, 582, and 584 of the act. The labeling regulations are considered by FDA to be cross referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

In the **Federal Register** of October 6, 2009 (74 FR 51287), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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