TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Type of Submission	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
202.1(e)(6)	Waiver request to FDA	1	1	1	12	12
202.1(j)(1)	Submission of advertisement to FDA for prior approval	1	1	1	2	2
202.1(j)(1)(iii)	Providing a program to FDA for assuring that adverse information about the drug will be publicized	1	1	1	12	12
202.1(j)(4)	Voluntarily submitting the advertisement to FDA prior to publication for comment	155	9.065	1,405	20	28,100
Total						28,126

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

TABLE 2.—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN[1]

21 CFR Section	Type of Submission	No. of Respondents	Annual Frequency per Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
202.1	Advertisements prepared in accordance with § 202.1	355	47.324	16,800	400	6,720,000
202.1(j)(1)	Including information about the drug's fatalities or serious damage in the advertisement	1	1	1	40	40
Total						6,720,040

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

Dated: March 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5812 Filed 3–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0380]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications

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 April 16, 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 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@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.

Product Jurisdiction: Assignment of Agency Component for Review of Premarket Applications—(OMB Control Number 0910–0523)—Extension

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Public Law 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for the premarket review and regulation of

products that are comprised of any combination of the following products: (1) A drug and a device; (2) a device and a biological product; (3) a biological product and a drug; or (4) a drug, a device, and a biological product. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designated to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as the basis for making the assignment or designation decision. Most information required by the regulation is already required for premarket applications affecting drugs, devices, biological products, and combination products. The respondents will be businesses or other for-profit organizations.

In the **Federal Register** of August 25, 2009 (74 FR 42900), 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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 3	43	1	43	24	1,032

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

These burden estimates are based on the number of applications FDA received over the past 2 fiscal years.

Dated: March 11, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–5749 Filed 3–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0497]

Agency Information Collection Activities; Submission for Office and Management and Budget Review; Comment Request; Abbreviated New Animal Drug Applications

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 April 16, 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–NEW and title "Abbreviated New Animal Drug Application." 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, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 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.

Abbreviated New Animal Drug Applications—FD&C Act/Section 512(n)(1)—(OMB Control Number 0910–NEW)

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Public Law 100–670). Under Section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review followed by the submission of an administrative ANADA when FDA finds that all the applicable technical sections for an ANADA are complete. FDA requests that an applicant accompany ANADAs and requests for phased review of data to support ANADAs with the Form FDA 356v to ensure efficient and accurate processing of information to support approval of the generic new animal drug.

In the **Federal Register** of November 2, 2009 (74 FR 56643), 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: