ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Total					850

Dated: March 11, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–5841 Filed 3–16–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities: Proposed Collection; Comment Request; Prescription Drug Advertisements

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements, including third party disclosure, contained in FDA's regulations on prescription drug advertisements.

DATES: Submit written or electronic comments on the collection of information by May 17, 2010.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, e-mail: *Elizabeth.Berbakos@fda.hhs.gov*.

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 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.

Prescription Drug Advertisements—21 CFR 202.1 (OMB Control Number 0910)—New

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(n)) (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, section 502(n) of the act requires advertisements to contain "a true statement" of certain information including "information in brief summary relating to side effects, contraindications, and effectiveness" as required by regulations issued by FDA. FDA's prescription drug advertising regulations at § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement." If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of the act (21 U.S.C. 352(n) and 321(n)), and FDA's implementing regulations at § 202.1(e).

Advertisements subject to the requirements at § 202.1 are subject to the PRA because these advertisements disclose information to the public. In addition, § 202.1(e)(6) and (j) include provisions that are subject to OMB approval under the PRA. The information collection requirements in § 202.1 have not previously been submitted to OMB for approval. With this notice, we are seeking comment on the proposed information collection.

Reporting to FDA

Section 202.1(e)(6) includes a provision that is subject to the PRA. Section 202.1(e)(6) permits a person who would be adversely affected by the enforcement of a provision of § 202.1(e)(6) to request a waiver from FDA for that provision. The waiver request must set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of § 202.1(e)(6) from which a waiver is sought, a complete copy of the

advertisement, and a showing that the advertisement is not false, lacking in fair balance or otherwise misleading, or otherwise violative of section 502(n) of the act.

FDA has not received any waiver requests under § 202.1(e)(6) in the past 10 years. However, we estimate for the purposes of this information collection that FDA would receive one waiver request annually under § 202.1(e)(6). The hours per response is the estimated time that a respondent would spend preparing information to be submitted to FDA under § 202.1(e)(6). Based on its experience reviewing other waiver requests, FDA estimates that approximately 12 hours on average would be needed per submission, including the time it takes to prepare, assemble, and copy the necessary information.

Section 202.1(j), which sets forth requirements for the dissemination of advertisements subject to the standards in § 202.1(e), contains the following information collection that is subject to the PRA:

Under § 202.1(j)(1), a sponsor must submit advertisements to FDA for prior approval before dissemination if: (1) The sponsor or FDA has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage; (2) FDA has notified the sponsor that the information must be part of the advertisements for the drug; and (3) the sponsor has failed to present to FDA a program for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements, or if such a program has been presented to FDA but is not being followed by the sponsor. Under § 202.1(j)(1)(iii), a sponsor must provide to FDA a program for assuring that significant new adverse information about the drug that becomes known (i.e., use of drug may cause fatalities or serious damage) will be publicized promptly and adequately to the medical profession in any subsequent advertisements.

Under § 202.1(j)(4), a sponsor may voluntarily submit advertisements to FDA for comment prior to publication.

FDA has not received any advertisements requiring prior approval under § 202.1(j)(1) in the past 10 years. However, we estimate for the purposes of this information collection that FDA would receive one advertisement requiring prior approval annually under § 202.1(j)(1). The hours per response is the estimated time that a respondent would spend preparing information to be submitted to FDA under § 202.1(j)(1). Based on its experience reviewing other advertisements, FDA estimates that approximately 2 hours on average would be needed per submission, including the time it takes to prepare, assemble, and copy the necessary information.

FDA has not received any program information required under § 202.1(j)(1)(iii) in the past 10 years. However, we estimate for the purposes of this information collection that FDA would receive one submission of program information annually under § 202.1(j)(1)(iii). The hours per response is the estimated time that a respondent would spend preparing information to be submitted to FDA under § 202.1(j)(1)(iii). Based on its experience reviewing advertisement-related information, FDA estimates that approximately 12 hours on average would be needed per submission, including the time it takes to prepare, assemble, and copy the necessary information.

Based on FDA data, the Center for Drug Evaluation and Research (CDER) estimates that approximately 1,150 draft promotional pieces are received from approximately 125 companies annually for agency comment prior to publication under § 202.1(j)(4), the Center for Biologics Evaluation and Research (CBER) estimates that approximately 250 draft promotional pieces are received from approximately 25 companies annually under § 202.1(j)(4), and the Center for Veterinary Medicine (CVM) estimates that approximately 5 draft promotional pieces are received from approximately 5 companies annually under § 202.1(j)(4). FDA anticipates that this submission rate will moderately increase in the near future. The estimated total number of submissions under § 202.1(j)(4) is 1,405. The hours per response is the estimated time that a respondent would spend preparing the information to be submitted to FDA under § 202.1(j)(4). Based on its experience reviewing advertisements submitted prior to publication for agency comment, FDA estimates that approximately 20 hours on average would be needed per submission, including the time it takes to prepare, assemble, and copy the necessary information.

Disclosures to the Public

Under § 202.1, advertisements for human and animal prescription drug and biological products must comply with the standards described in that section.

Based on FDA data, CDER estimates that approximately 15,000 advertisements for prescription drugs, including print and broadcast advertisements, are prepared by approximately 300 companies under § 202.1 annually, CBER estimates that approximately 1,000 of these advertisements are prepared by approximately 30 companies annually, and CVM estimates that approximately 800 of these advertisements are prepared by approximately 25 companies annually. FDA anticipates that this estimate will moderately increase in the near future. The estimated total number of advertisements under § 202.1 is 16,800. The hours per response is the estimated time that a respondent would spend preparing an advertisement subject to § 202.1. Based on its experience reviewing advertisements, FDA estimates that approximately 400 hours on average would be needed per advertisement, including the time it takes to prepare, assemble, and copy the necessary information.

Under § 202.1, if information that the use of a prescription drug may cause fatalities or serious damage has not been widely publicized in the medical literature, a sponsor must include such information in the advertisements for that drug. FDA is not aware of any advertisements that required inclusion of information on fatalities or serious damage associated with use of the drug under § 202.1(j)(1) in the past 10 years. However, we estimate for the purposes of this information collection that one advertisement would require inclusion of such information annually under § 202.1(j)(1). The hours per response is the estimated time that a respondent would spend preparing information to comply with § 202.1(j)(1). Based on its experience reviewing changes to advertisements, FDA estimates that approximately 40 hours on average would be needed to comply with § 202.1(j)(1), including the time it takes to prepare the necessary information.

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

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