substantial equivalence (21 U.S.C. 387e(j)). In a level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act, and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

Estimation of Burden

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FD&C Act sections	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
905(j) and 910(a)	150	1	150	360	54,000
Total					54,000

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

FDA has based these estimates on information related to other regulated products and FDA's expectations regarding the tobacco industry's use of the 905(j) pathway to market their products. Table 1 of this document describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387e(j) and 387j(a)). FDA estimates that it will receive 150 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 54,000 hours.

Dated: January 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1276 Filed 1–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertisements

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 23, 2011.

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 "Prescription Drug Advertisements". Also include the FDA 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. *Elizabeth.Berbakos@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.

Prescription Drug Advertisements—(OMB Control Number 0910)—New

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(n)) 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 FD&C 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 FD&C Act, (21 U.S.C. 352(n) and section 201 of the FD&C Act (21 U.S.C. 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 FD&C 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.

In the **Federal Register** of March 17, 2010 (75 FR 12756), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment.

The comment said that any waiver requests FDA receives in the future under § 202.1(e)(6) should be granted only for extraordinary reasons because

of the "high public interest value associated with parties fully complying with information requests concerning prescription drugs."

FDA Response: FDA is not aware of any request for a waiver under § 202.1(e)(6). If we receive such a waiver request in the future, we will consider this comment in determining whether or not to grant the request.

Concerning the statement that FDA has not received any advertisements requiring prior approval under § 202.1(j)(1) in the past 10 years, the comment said this may be indicative of FDA's failure to ensure compliance with this provision, rather than simply an indication that no advertisements are received under § 202.1(j)(1). The comment said that FDA should more vigorously investigate and penalize or otherwise sanction sponsors who fail to ensure that significant new adverse information about a drug that becomes known to the sponsors is advertised in compliance with § 202.1(j).

FDA Response: FDA properly enforces the requirements of § 202.1(j). Additionally, the Division of Drug Marketing, Advertising and Communication (DDMAC) works closely with the Office of New Drugs (OND) and sponsors to ensure that information about serious and significant risks that have not been widely publicized is appropriately presented in promotional labeling and advertising. FDA regularly communicates these requests to sponsors through supplement letters sent by OND review divisions and safety update letters sent by DDMAC. DDMAC is not aware of any drugs that have required prior approval under § 202.1(j)—but DDMAC is consistently in contact with OND and sponsors to ensure that promotional labeling accurately communicates serious and significant risk 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	Number 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	1,395	20	27,900
Total						27,926

[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	Number of respondents	Annual frequency of disclosure	Total annual disclosure	Hours per disclosure	Total hours
202.1	Advertisements prepared in accordance with § 202.1.	355	47	16,685	400	6,674,000
202.1(j)(1)	Including information about the drug's fatalities or serious damage in the advertisement.	1	1	1	40	40
Total						6,674,040

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

Dated: January 14, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–1275 Filed 1–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0381]

Generic Drug User Fee; Notice of Public Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 23, 2011, the comment period for the notice of public meeting entitled Generic Drug User Fee; Public Meeting; Request for Comments, published in the **Federal Register** of August 9, 2010 (75 FR 47820). In that notice, FDA announced a public meeting that took place on September 17, 2010, to gather stakeholder input on the development of a generic drug user fee program. FDA is reopening the comment period to permit public consideration of late-received comments and to provide an opportunity for all interested parties to provide information and share views on the matter.

DATES: Submit either electronic or written comments by February 23, 2011.