PRESCRIPTION DRUG ADVERTISEMENTS
OMB Control No. 0910-New
SUPPORTING STATEMENT

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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 202.1(j) include provisions that are subject to OMB approval under the

PRA.

2. Purpose and Use of the Information Collection

FDA's prescription drug advertising regulations at § 202.1 describe requirements and standards for print and broadcast advertisements and implements section 502(n) of the act, which requires advertisements to contain "a true statement" of certain information including "information in brief summary relating to side effects, contraindications, and effectiveness." The information collection in § 202.1 results from FDA's statutory responsibility to ensure that prescription drug advertisements comply with the statute and regulations.

3. Use of Improved Information Technology and Burden Reduction

FDA has issued several guidance documents to assist manufacturers in complying with § 202.1. These guidance documents are available at FDA's web site http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

4. Efforts to Identify Duplication and Use of Similar Information

The requirements do not duplicate nor are they similar to any current requirements.

5. Impact on Small Businesses or Other Small Entities

The Small Business Administration (SBA) defines as small any pharmaceutical preparations manufacturing entity (NAICS 325412) with fewer than 750 employees and any biologics product manufacturing entity (NAICS 325414) with fewer than 500 employees. Among the 48 companies submitting television or radio advertisements to FDA in 2008, for example, only about 5 would meet the SBA definition of small entity. Thus, we estimate that only a few of the manufacturers affected by

these regulations would be a small business.

6. Consequences of Collecting the Information Less Frequently

There is no prescribed frequency for submitting this information. FDA issued these regulations in response to section 50(n) of the act. Any less frequent collection of information would be in conflict with the statutory requirements.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances relating to this provision.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of March 17, 2010 (75 FR 12756), FDA published a 60-day notice requesting comment on this information collection. 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 ten 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.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents associated with these regulations.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under these requirements is protected under 21 CFR 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Justification for Sensitive Questions

There are no sensitive questions associated with these regulations.

12a. Estimates of Annualized Hour Burden

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

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	1,405	20	28,100
Total						28,126

Table 2.--Estimated Annual Third Party Disclosure Burden

21 CFR Section	Type of Submission	Number of Respondents	Annual Frequency per Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
202.1	Advertisements	355	47	16,685	400	6,674,000

	prepared in accordance with § 202.1					
202.1(j)(1)	Including information about the drug's fatalities or serious damage in the advertisement	1	1	1	40	40
Total						6,674,000

12b. Estimates of Annualized Burden Costs –

Type of Respondent	Total Hours	Hourly Wage Rate	Total Costs
Industry labor cost	6,702,166	88.00	$589,790,608

The industry burden estimate calculated above would result in labor costs. Using a wage rate of $88 per hour for loaded industry labor costs, times 6,702,166 hours calculated above for the information collection resulting from § 202.1, equals $589,790,608 in labor costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

There are no other costs, including capital costs or operating and maintenance costs that would result from this information collection.

14. Annualized Cost to the Federal Government

FDA currently devotes approximately 37 FTEs to the review of submissions required under 21 CFR 202.1.

15. Explanation for Program Changes or Adjustments

This is a request for a new OMB number for this collection of information which has been operating in violation.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication and project time scheduling.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration data will be displayed where required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no new FDA forms or publications associated with these regulations.