Prescription Drug Advertisements

0910-0686

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

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.

2. Purpose and Use of the Information Collection

FDA's prescription drug advertising regulations in § 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.

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 website. 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 502(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 accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of February 27, 2014 (79 FR 11112).We received no comments that pertained to the information collection.

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.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

Reporting to FDA

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.

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.

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.

Under § 202.1(j)(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 estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	Number of	Number of	Total	Average	Total

	respon-dents	responses per respondent	annual responses	burden per response	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	113	6	678	20	13,560
Total					13,586

Table 2.--Estimated Annual Third-Party Disclosure Burden

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
202.1-Advertisements prepared in accordance with § 202.1	541	46.5	25,157	400	10,062,800
202.1(j)(1)- Including information about the drug's fatalities or serious damage in the advertisement	1	1	1	40	40
Total					10,062,840

12b. Annualized Cost Burden Estimate

The industry burden estimate calculated above would result in labor costs. Using a wage rate of $75 per hour for industry labor costs, times 100,516,266,748,166 hours calculated above for the

information collection resulting from § 202.1, equals $753,872,006 in labor costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

There are no other capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA currently devotes approximately 38 FTEs to the review of submissions required under 21 CFR 202.1. Assuming each FTE is approximately $150,000, the total cost is approximately $5,700,000.

15. Explanation for Program Changes or Adjustments

The total burden hours has increased from 6,702,166 hours to 10,076,426. This is the result of an increase in submissions over the last 3 years under these advertising regulations.

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 exceptions to the certification.