FOOD AND DRUG ADMINISTRATION
Prescription Drug Advertisements
OMB Control No. 0910-0686

SUPPORTING STATEMENT

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations. Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act, FFDCA) (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).

Accordingly, FDA is requesting OMB approval of the information collection provisions found in the regulations regarding prescription drug advertisements as codified in 21 CFR Part 202: *Prescription Drug Advertising*.

2. Purpose and Use of the Information Collection

The information collection implements section 502(n) of the FFDCA, which describes requirements and standards for print and broadcast advertisements. The statute is codified at 21 CFR 202.1 and applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. The information collection allows FDA to determine compliance with the 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 website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

According to the Small Business Administration (SBA), "small" is 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. We therefore estimate that 5 entities may be impacted. At the same time, compliance with the regulations ensures protection of the public health and thus the regulations provide for no exemptions from the requirements.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements of the FFDCA.

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

There are no special circumstances relating to the information collection.

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 May 23, 2017 (82 FR 23574). While we received one comment in response to the notice, it did not respond to any of the four information collection topics solicited in the notice and was therefore not addressed in our 30 day notice, nor here in this supporting statement.

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 the information collection.

12. Estimates of Annualized Hour Burden and Costs

12a. *Annualized Hour Burden Estimate*

We estimate the burden associated with the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section or Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER:					
202.1(e)(6); waiver request	1	1	1	12	12
202.1(j)(1); submission of advertisement	1	1	1	2	2
202.1(j)(1)(iii); assuring that adverse information be publicized	1	1	1	12	12
202.1(j)(4); voluntary submission of ad to FDA	71	6.97	495	20	9,900
CBER:					
202.1(e)(6); waiver request	0	0	0	12	0
202.1(j)(1); submission of advertisement	0	0	0	2	0
202.1(j)(1)(iii); assuring that adverse information be publicized	0	0	0	12	0
202.1(j)(4); voluntary submission of ad to FDA	9	8	72	20	1,440
CVM:					
202.1(e)(6); waiver request	0	0	0	12	0
202.1(j)(1); submission of advertisement	0	0	0	2	0
202.1(j)(1)(iii); assuring that adverse information be publicized	0	0	0	12	0
202.1(j)(4); voluntary submission of ad to FDA	5	1	5	20	100
Total					11,466

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

Table 2.--Estimated Annual Third-Party Disclosure Burden[1, 2]

21 CFR Section or Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Burden per Disclosure	Total Hours
CDER:					
202.1; ad prepared in accordance with 21 CFR Part 202	394	105.3	41,494	400	16,597,600
202.1(j)(1); info. included re. fatalities or serious damage	1	1	1	40	40
CBER:					
202.1; ad prepared in accordance with 21 CFR Part 202	47	63.4	2,984	400	1,193,600
202.1(j)(1); info. included re. fatalities or serious damage	0	0	0	40	0
CVM:					
202.1; ad prepared in accordance with 21 CFR Part 202	25	36	900	400	360,000
202.1(j)(1); info. included re. fatalities or serious damage	0	0	0	40	0
Total					18,151,240

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

[2] Numbers rounded to the nearest one/one-hundredth.

Reporting to FDA

Section 202.1(e)(6) provides for certain waivers. 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.

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.

Third Party 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.

12b. *Annualized Cost Burden Estimate*

For the estimated annualized cost to industry we use a wage rate of $75 per hour for labor costs multiplied by the total number of burden hours calculated above (18,162,706), which results in $1,362,202,950.

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

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

14. Annualized Cost to the Federal Government

FDA currently has allocated approximately 38 FTEs to the review of submissions required by the information collection. We use a fully-loaded labor cost of $150,000 for each FTE, for a total estimated cost to the Federal Government of $5,700,000.

15. Explanation for Program Changes or Adjustments

The information collection reflects agency adjustments. While the number of annual burden hours increased from 10,076,426 hours to 18,162,706 hours (**+8,086,280**), the number of annual responses has decreased from 25,839 to 21,804 (**-4,035**). We attribute the increase to an increase in third party disclosures, where there is decrease in the number of submissions under 21 CFR 202.1(j)(4). Also, FDA has consolidated the IC list appearing at www.reginfo.gov by consolidating the previously itemized regulatory provisions into reporting and third party disclosure categories. We believe this will assist the reader by more easily identifying the summary of cumulative fluctuations for the collection. At the same time, readers may still view estimated burden associated with individual provisions by referring to the agency's 60-day and 30-day notices and in the burden tables found in Q.12: *Estimates of Annualized Burden Hours and Costs* of this supporting statement.

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 as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no new exceptions to the certification.