PRESCRIPTION DRUG ADVERTISEMENTS
21 CFR PART 202

OMB Control No.0910-0686 – Revision

RIN 0910-AG27: *Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, and Neutral Manner in Advertisements in Television and Radio Format – Final Rule*

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) rulemaking. 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 (firms) 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.

Currently, prescription drug advertising regulations in § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Print advertisements must include a brief summary relating to side effects and contraindications from the product's approved package labeling (§ 202.1(e)(1)). Advertisements broadcast through media such as television and radio must disclose the major side effects and contraindications (commonly called the "*major statement*") of the advertised product in either the audio or audio and visual parts of the presentation and make adequate provision for dissemination of the approved or permitted package labeling *or* must contain a brief summary of all necessary information related to side effects and contraindications (§ 202.1(e)(1)). We are amending the regulations to implement section 502(n) of the FD&C Act regarding direct-to-consumer (DTC) advertisements for human prescription drugs presented in television (TV) or radio format and stating the name of the drug and its conditions of use. The regulation does not change current requirements for any prescription drug advertisement for animals, nor does it change disclosure requirements for print prescription drug advertisements for humans.

We therefore request OMB approval for the information collection provisions set forth in this final rule and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

As required by the regulation, in DTC advertisements for human prescription drugs presented in TV or radio format and stating the name of the drug and its conditions of use (DTC TV/radio ads), the disclosure of the major statement in a presentation that is clear, conspicuous, and neutral is important to help consumers notice, attend to, and understand a drug's risks as well as its benefits. The information collection helps implement standards that FDA will use to determine whether DTC TV/radio ads comply with the statutory requirements to present the major statements for human prescription drugs in a clear, conspicuous, and neutral manner. Improving consumer understanding of the major statement helps to ensure that DTC TV/radio ads convey a truthful and non-misleading net impression about the advertised drug and help ensure that consumers are better informed when they participate in healthcare decision making. The disclosures in this regulation are for firms that choose to advertise their human prescription drug products in DTC TV/radio ads. If advertisements fail to include the required disclosure or if the disclosure minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of section 502(n) of the FD&C Act (21 U.S.C. 352(n) and section 201(n) of the FD&C Act (21 U.S.C. 321(n)) and FDA's implementing regulations at § 202.1(e).

3. Use of Improved Information Technology and Burden Reduction

We receive postmarket submissions of promotional material using Form 2253 ("*Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use*"), approved under Control Nos. 0910-0001 and 0910-0338. Information is submitted using the electronic common technical document (eCTD) portal available on our website.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. In accordance with 44 U.S.C. 3507(d)(1), 5 CFR 1320.11, FDA submitted its ICR for the companion proposed rule on April 19, 2010. Although OMB assigned control number of 0910-0835 in its notice of action, we subsequently established control no. 0910-0686 to include information collection activity associated with prescription drug advertising regulations in § 202.1.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. Nevertheless, in light of our determination that under the Small Business Regulatory Enforcement Fairness Act this rule will have a significant economic impact on a substantial number of small entities, we will publish a Small Entity Compliance Guide to assist small entities in complying with the final rule. In addition, having received comments that firms would need more time to comply with the new regulatory requirements, we extended the compliance and effective dates. Additionally, we maintain small business assistance offices within the agency, and have established assistance programs within our regional offices to provide small business assistance in complying with FDA regulations.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 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 the Federal Register of March 29, 2010 (75 FR 15376), we published a proposed rule, including an analysis of the information collection, and solicited public comment (docket no. FDA-2009-N-0582). We provided additional opportunities for public comment in the Federal Registers of January 27, 2012 (77 FR 4273), and March 23, 2012 (77 FR 16973). We discuss the comments received in section V, "*Comments on the Proposed Rule and FDA Response*," of the final rule. Although we did not revise our burden estimates in response to these comments, we have updated our figures to reflect current data on the number of advertisements expected annually.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR does not collect personally identifiable information (PII) or information of a personal nature. Because the regulations do not request or require submission of information, we provide no assurance of confidentiality to respondents. Rather, the information collection sets forth standards for presenting the major statement in a clear, conspicuous, and neutral manner in DTC TV/radio ads. It covers third-party disclosures for advertisements presented in TV and radio format that are submitted to FDA. Because neither FDA nor any party acting on behalf of the agency collects PII, this ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection for do not apply.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.—Estimated Burden Resulting from Revising DTC TV/radio ads to comply with 21 CFR 202.1(e)(1)

21 CFR 202.1 – Prescription Drug Marketing	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Hourly Burden per Disclosure	Total Hours
One-time activities: reading and understanding rule, revising company SOPs, modifying existing ads (if necessary)	57	3	171	2.5	427.5
202.1(e)(1)(ii): Ongoing implementation of revised requirements for future DTC TV and Radio ads	57	11.02	628	5	3,140
TOTAL			0		0

We estimate a one-time burden of 427.5 hours for reading and understanding the rule, revising associated SOPs, and modifying existing ads.

We also estimate an increase to the average annual burden respondents will incur for complying with the requirements in 202.1(e)(1)(ii). Using the number of advertisements routinely submitted in Form 2253 ("*Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use*," approved in OMB Control Numbers 0910-0001 and 0910-0338) in 2020 as a basis, we assume 57 firms will develop and disseminate an average of 628 TV/radio advertisements, including advertisements for biologic products, annually. We also assume an average of 5 hours is required to prepare these advertisements in accordance with requirements in 21 CFR 202.1. Included in our count are only those respondents we believe disseminate marketing information pertaining to human prescription drugs directly to the consumer through television or radio advertisements.

12b. Annualized Cost Burden Estimate

To calculate annual cost burden, we assume wage rates of $75/hour and $150/hour for a marketing specialist and marketing manager, respectively.[1] Assuming each advertisement would require 3 hours of marketing specialist time and 2 hours of marketing management time, we calculate annual burden costs of $329,700.

[1] Bureau of Labor Statistics, "Occupational Employment Statistics: May 2020 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 325400 – Pharmaceutical and Medical Manufacturing," https://www.bls.gov/oes/current/naics4_325400.htm. Wages are doubled to account for employee benefits and overhead costs.

Table 2. Annual Cost for Ensuring Advertisements Meet the Standards of this Final Rule

21 CFR Part 202.1 Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Marketing specialist	1,884	$75	$141,300
Marketing Manager	1,256	$150	$188,400
Total			$329,700

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

All firms may incur one-time costs for revising SOPs. Consistent with our Final Regulatory Impact Analysis (FRIA), we estimate these one-time costs to range from $1.1 million to $2.4 million.

14. Annualized Cost to the Federal Government

Review of prescription drug labeling is conducted as part of the agency's ongoing postmarket monitoring activities. While some costs are absorbed through user fees collected annually under authority of the Prescription Drug User Fee Act (PDUFA), FDA has budgeted $5.6 million annually to the postmarket monitoring of marketed drug products, including the cost of this rulemaking.

15. Explanation for Program Changes or Adjustments

As a result of the revised regulation implementing section 502(n)(3) of the FD&C Act, the rulemaking would revise our estimate to reflect an increase of 799 responses and 3,568 hours to the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

17. Display of OMB Expiration Date

FDA will display the OMB control number as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.