4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0363]

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

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: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0686. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@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 Advertising--21 CFR Part 202

This information collection supports Agency regulations and associated guidance. FDA protects the public health by assuring the safety, effectiveness, and security of a wide range of products. We also help consumers get accurate, science-based information they need to use medicines appropriately and improve their health. Section 301 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 331) prohibits the misbranding of FDA-regulated products, including prescription drugs. Section 502 of the FD&C Act (21 U.S.C. 352) requires that manufacturers, packers, and distributors, or anyone acting on their behalf (firms) include certain information in human prescription drug promotional labeling and advertisements.

Our prescription drug advertising regulations in part 202 (21 CFR part 202) 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).

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.

While the regulations establish requirements for prescription drug advertisements, we have developed the guidance document entitled, "Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements; Guidance for Industry" to clarify requirements for product name placement, size, prominence, and frequency in promotional labeling and advertisements for human and animal prescription drugs and prescription biological products. The guidance includes recommendations that pertain to traditional print promotional labeling and advertisements (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling (e.g., videos shown in a healthcare provider's office), broadcast advertisements (e.g., television advertisements, radio advertisements), and electronic and computer-based promotions (e.g., internet, social media, emails, CD-ROMs, DVDs). The guidance document was issued consistent with our Good Guidance Practice regulations in part 10.115 which provide for public

comment at any time, and is available from our website at: https://www.fda.gov/media/87202/download.

In the *Federal Register* of April 29, 2021 (86 FR 22686), we published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received, all generally supportive of FDA's drug advertising regulations; however, some commenters suggested FDA might do more to promote truthful advertising with regard to prescription drug products. We appreciate all comments. No comment suggested a revision to our current estimate for the information collection.

We estimate the burden of the information collection as follows:

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

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER Regulated Products:					
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	59	1.85	109	20	2,180
CBER Regulated Products:					
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	7	2.57	18	20	360
CVM Regulated Products:					
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	7	1	7	20	140
Total			143		2,758

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

Our estimate of burden we attribute to the reporting provisions in part 202 is based on our experience with the collection and a review of Agency data.

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

21 CFR Section; Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Burden per Disclosure	Total Hours
202.1; ad prepared in accordance with part 202	670	111.08	74,425	400	29,770,000
202.1(j)(1); info. included re. fatalities or serious damage	1	1	1	40	40
Total			74,426		29,770,040

[1] There are no capital costs or operating and maintenance costs associated with this collection.
[2] Numbers rounded to the nearest one/one-hundredth.

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. Based on a review of Agency data we estimate an average of 29,770,040 hours is incurred annually by respondents in complying with third-party disclosure requirements for prescription drug advertising. We assume a placeholder of 1 for disclosures under § 202.1(j)(1).

Table 3.--Estimated Annual Disclosure Burden Discussed in Agency Guidance

Information Collection Recommendations	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure (in hours)	Total Hours
Product name placement, size, and prominence in promotional labeling and advertisements' disclosures	715	190.3	136,069	3	408,207

The placement, size, prominence, and frequency of the proprietary and established names for human prescription drugs, including prescription biological products, and animal prescription drugs are specified in labeling and advertising regulations (§§ 201.10(g) and (h); 202.1(b)-(d)). Based on Agency data, we estimate that, for human and animal prescription drugs and prescription biological products, an average of 715 firms disseminate approximately 136,069 advertisements and promotional pieces each year. We assume that the burden associated with complying with the regulatory requirements discussed in the guidance would be approximately 3 hours per response.

We have adjusted our estimate upward to reflect increases in prescription drug

advertisements and associated disclosures.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-15648 Filed: 7/22/2021 8:45 am; Publication Date: 7/23/2021]