4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-2613]

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, Agency, or we) 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 (PRA).

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

OMB Control Number 0910-0686--Revision

This information collection supports FDA implementation of Agency regulations and associated guidance. Section 502(n) of the Federal Food, Drug, and Cosmetic Act (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. FDA's prescription drug advertising regulations in § 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).

We are revising the information collection to include recommendations found in Agency guidance. The guidance document entitled, "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer [DTC] Promotional Labeling and Advertisements," provides content and format recommendations for DTC promotional labeling and advertisements (promotional communications) that present quantitative efficacy and risk information. The guidance document was developed consistent with Agency good guidance practices regulations in 21 CFR 10.115, which provide for comment at any time. The draft guidance document, issued

on October 17, 2018, is available at https://www.fda.gov/media/117573/download and in docket FDA-2018-D-2613. FDA also maintains a searchable guidance database at https://www.fda.gov/regulatory-information/search-fda-guidance-documents to facilitate access to these documents.

The guidance document recommends specific content elements pertaining to the presentation of quantitative efficacy and risk information in DTC promotional communications. The guidance also discusses formatting considerations related to the use of visual aids that display quantitative efficacy or risk information in DTC promotional communications. The guidance document explains that the information collection applies to the third-party disclosure of information pertaining to FDA-regulated products that contain quantitative efficacy or risk information and discusses the Agency's current thinking with regard to this topic.

In the *Federal Register* of October 17, 2018 (83 FR 52484), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received regarding FDA's need for the information, the accuracy of our burden estimate, or ways to minimize burden. Although we are preparing to finalize the guidance document to clarify considerations for quantitative efficacy or risk presentations across various media types and provide additional explanation regarding specific concepts and examples that were included in the draft guidance, none of the revisions pertain to the information collection recommendations discussed in our 60-day notice.

We estimate the burden of this collection of information as follows:

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

Guidance Document Recommendations	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
"Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements" as recommended in Section III of the guidance.	465	43	19,995	2	39,990

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

According to available data, approximately 465 firms prepare 49,000 FDA-regulated DTC promotional communications annually. Of these communications, we assume 40 percent contain a disclosure of quantitative efficacy or risk information. Based on this information, we calculate that firms each disseminate 43 DTC promotional communications that contain a disclosure of quantitative efficacy or risk information annually. Based on our experience reviewing FDA-regulated promotional communications for drugs, we estimate respondents spend an average of 2 hours to prepare a disclosure as recommended in the guidance. We therefore estimate 19,995 disclosures and a burden of 39,990 hours annually.

Dated: March 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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