recommendation, to *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.*

Dated: April 23, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08992 Filed 4–28–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0363]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with prescription drug advertising.

DATES: Submit either electronic or written comments on the collection of information by June 28, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 28, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 28, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0363 for ''Prescription Drug Advertising.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice

of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug Advertising—21 CFR Part 202

OMB Control Number 0910–0686—Extension

This information collection supports Agency regulations and associated guidance. The Food and Drug Administration (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 health care 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.*

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number 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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
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	Number of respondents	Number 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	Number of respondents	Number 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), (c), and (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 by 11,705,225 hours annually to reflect increases in prescription drug advertisements and associated disclosures.

Dated: April 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–08948 Filed 4–28–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0073]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.