ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Implementation interview: Additional center staff	60	1	.5	30
Cost workbook	50	1	7.5	375
Time use survey staff roster	50	1	.25	13
Time use survey advance letter	700	1	.08	56
Time use survey	560	1	.25	140

Estimated Total Annual Burden Hours: 954 hours.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–10525 Filed 5–22–17; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

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

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 the reporting requirements, including third party disclosure, contained in FDA's current regulations on prescription drug advertisements.

DATES: Submit either electronic or written comments on the collection of information by July 24, 2017.

ADDRESSES: You may submit comments as follows:

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2010–N–0110 for ''Prescription Drug Advertisements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- 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 Division of Dockets Management. 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.gpo.gov/fdsys/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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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 Advertisements; OMB Control Number 0910–0686—Extension

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 (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 section 502(n) of the FD&C Act, section 201(n) of the FD&C Act (21 U.S.C. 321(n)), and FDA's implementing regulations at § 202.1(e).

Advertisements subject to the requirements at § 202.1 are subject to the PRA because these advertisements disclose information to the public. In addition, § 202.1(e)(6) and (j) include provisions that are subject to OMB approval under the PRA.

Reporting to FDA

Section 202.1(e)(6) permits a person who would be adversely affected by the enforcement of a provision of § 202.1(e)(6) to request a waiver from FDA for that provision. 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, misleading, or otherwise violative of section 502(n) of the FD&C Act.

Section 202.1(j), which sets forth requirements for the dissemination of advertisements subject to the standards in § 202.1(e), contains the following information collection that is subject to the PRA:

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.

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section or activity	Number of respondents	Number 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]

21 CFR section or activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	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.

Dated: May 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–10533 Filed 5–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1848]

Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 provisions in FDA's cosmetic labeling regulations.

DATES: Submit either electronic or written comments on the collection of information by July 24, 2017.

ADDRESSES: You may submit comments as follows: