Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Grantees	51	1	100	5,100
Sub-Grantees (in states with sub-grantee managed systems)	[1] 200	1	80	16,000
Large Energy Vendors (largest 5 electric, 5 gas, 10 fuel oil, and 10 propane vendors per state—average)	[1] 1,530	1	40	61,200
Small Energy Vendors (excluded except in special circumstances)	200	1	10	2,000
Total Annual Burden Hours	1,981	1	([2])	84,300

[1] Estimate.
[2] Varies.

The following burden estimates pertain to the grantee survey section of the form:

ANNUAL BURDEN ESTIMATES FOR LIHEAP PERFORMANCE DATA FORM: PART I—LIHEAP GRANTEE SURVEY

	Number of respondents	Number of responses per respondent	Average hour burden per response	Total burden hours
Grantees	51	1	3.5	178.50

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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–13031 Filed 6–4–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0627]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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: Fax written comments on the collection of information by July 7, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0183. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions—(OMB Control Number 0910–0183)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every Agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Section 10.30 (21 CFR 10.30) sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20) (Submission of documents to Division of Dockets Management), a citizen petition requesting the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions, or groups.

Section 10.33 (21 CFR 10.33) issued under section 701(a) of the Federal,

Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner on a petition submitted under 21 CFR 10.25 (Initiation of administrative proceedings). A petition for reconsideration must contain a full statement in a well-organized format of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision involved. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals of households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting from the Commissioner of FDA a reconsideration of a matter.

Section 10.35 (21 CFR 10.35), issued under section 701(a) of the FD&C Act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (Submission of documents to Division of Dockets Management), the Commissioner to stay the effective date of any administrative action.

Such a petition must do the following: (1) Identify the decision involved; (2) state the action requested, including the length of time for which a stay is requested; and (3) include a statement of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for stay of action.

Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85 (21 CFR 10.85), issued under section 701(a) of the FD&C Act sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (Submission of documents to Division of Dockets Management), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request.

Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the Agency's formal position for matters of general applicability.

In the **Federal Register** of March 20, 2014 (79 FR 15594), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.30	207	1	207	24	4,968
10.33	4	1	4	10	40
10.35	5	1	5	10	50
10.85	4	1	4	16	64
Total					5,122

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

The burden estimates for this collection of information are based on Agency records.

On December 19, 2013, FDA published a technical amendment (78 FR 76748) announcing that the Agency is modernizing its administrative regulations regarding submission of citizen petitions to explicitly provide for electronic submission. The current regulation does not recognize electronic methods for submitting citizen petitions; thus, this action will enable efficiency and ease in the filing of citizen petitions.

The Agency still allows for non-electronic submissions; however, electronic submissions of a citizen petition to a specific electronic docket presents a simpler and more straightforward approach. FDA has created a single docket on *http://www.regulations.gov*, the U.S. Government's consolidated docket Web site for Federal Agencies, for the initial electronic submission of all citizen petitions. The FDA Electronic Method for Submission of Citizen Petitions Docket, Docket No. FDA 2013–S–0610, allows the petitioner to create an electronic submission through *http://www.regulations.gov* and provides an alternative to the current system of submission for citizen petitions.

Electronic submissions through *http://www.regulations.gov* will provide the submitter with an immediate record of the time of submission. FDA's Division of Dockets Management (DDM) (*http://www.fda.gov/RegulatoryInformation/Dockets/default.htm*) will continue to inform the submitter of formal filing; however, tracking will be more easily accomplished through electronic submission.

DDM will receive the electronically submitted citizen petition through the Federal Dockets Management System, the Agency component of *http://www.regulations.gov*. Subsequently, DDM will review the electronic submission and when it accepts the citizen petition for filing, DDM will assign a docket number to that petition, different from the FDA electronic submission docket number. This unique docket number from DDM identifies the docket for that particular citizen petition for all future filings and submissions related only to that citizen petition. Subsequent submissions associated with that citizen petition will refer to the assigned unique docket number. The advantage to this change is that it ensures efficiency and ease in

communication, quicker interaction between citizen petitioners and FDA, and easier access to FDA to seek input through the citizen petition process.

Dated: May 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13037 Filed 6–4–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0110]

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

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: Fax written comments on the collection of information by July 7, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0686. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 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 Paperwork Reduction Act of 1995 (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 or otherwise 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.

In the **Federal Register** of February 27, 2014 (79 FR 11112), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: