at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to the State of Washington announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Robin Arnold-Williams, Secretary, Department of Social and Health Services, P.O. Box 45010, Olympia, WA 98504–5010.

Dear Ms. Arnold-Williams:

I am responding to your request for reconsideration of the decision to disapprove the Washington Medicaid State plan amendment (SPA) 08–002, which was submitted on January 7, 2008, and disapproved on September 26, 2008. The SPA proposed to add a methodology to the State plan that would be used in the event that a contract with Regional Support Network to provide mental health services under a managed care delivery system to the State of Washington was not continued.

The issues to be considered at the hearing are:

• Whether the proposed effective date for the SPA was consistent with the limitations imposed by applicable appropriations statutes on the availability of funding for SPAs, the requirements of sections 1902(a)(4)(A) and 1902(a)(30)(A) of the Social Security Act (the Act) relating to methods and procedures generally and for payment rates specifically, and the implementing regulations at 42 CFR 430.20 and 42 CFR 447.205—which require advance public notice of changes in payment rates. The State's proposed effective date for the SPA was earlier than the date of the publication of the public notice that the State submitted in support of the SPA.

• Whether Washington provided adequate documentation to document the proposed payment rates and demonstrate that the proposed rates were consistent with efficiency and economy as required by section 1902(a)(30)(A) of the Act. Specifically, the State proposed the use of actuarially developed rates that included a range of rates as opposed to a single dollar amount. The State indicated that the single dollar amount was developed from the above mentioned rate range, however, they were not able to provide either the dollar amount or the documentation regarding the construction of the single rate.

I am scheduling a hearing on your request for reconsideration to be held on February 5, 2009, at the Centers for Medicare & Medicaid Services Seattle Regional Office, 2201 Sixth Avenue, MS/RX–43, Seattle, Washington 98121, in order to reconsider the decision to disapprove SPA 08–002. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by Federal regulations at 42 CFR Part 430.

I am designating Mr. Benjamin Cohen as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786–3169. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing.

Sincerely,
Kerry Weems,
Acting Administrator.

Section 1116 of the Social Security Act (42 U.S.C. section 1316; 42 CFR section 430.18).

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: December 22, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–31019 Filed 12–29–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0650]

Agency Information Collection Activities; Proposed Collection; 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 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 the reporting requirements contained in existing FDA regulations regarding the general administrative procedures for a person to petition the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a rule; to file a petition for an administrative reconsideration or an administrative stay of action; and to request an advisory opinion from the Commissioner.

DATES: Submit written or electronic comments on the collection of information by March 2, 2009.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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.

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 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 and businesses or other 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 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 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 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	162	3	486	12	5,832
10.33	4	2	8	10	80
10.35	7	2	14	10	140
10.85	2	1	2	16	32
Total					6,084

[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 and experience over the past 3 years. In 2007, FDA received approximately 162 citizen petitions (§ 10.30), 4 administrative reconsiderations of action (§ 10.33), 7 administrative stays of action (§ 10.35), and 2 advisory opinions (§ 10.85).

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a

Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–31058 Filed 12–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0451] (formerly Docket No. 2007N–0321)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast 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. Due to an administrative error, this document is being republished.

DATES: Fax written comments on the collection of information by January 29, 2009.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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.

Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the act.

FDA regulations require that advertisements that make claims about a prescription drug include a ''fair balance'' of information about the benefits and risks of advertised products, in terms of both content and presentation. Ads can present information in ways that can optimize or skew the relative balance of risks and benefits. Both healthcare providers and consumers have expressed concerns to FDA about the effectiveness of its regulation of manufacturers' Direct-to-Consumer (DTC) prescription drug advertising, especially as it relates to assuring balanced communication of risks compared with benefits.

One characteristic of DTC television broadcast ads is the use of compelling visuals. Many assert that the visuals present during the product risk presentation are virtually always positive in tone and often depict product benefits. A consistently raised question is whether advertising visuals of benefits interferes with consumers' understanding and processing of the risk information in the ad's audio or text.

The manner in which required risk information is presented in DTC ads has been recently addressed in the Food and Drug Administration Amendments Act of 2007 (FDAAA). Section 901(3) of FDAAA states that the major statement in DTC broadcast ads ''shall be presented in a clear, conspicuous and neutral manner.'' Further, the Secretary of Health and Human Services ''shall establish standards for determining whether the major statement is presented in such a manner.'' FDAAA does not define how the objective of ''clear, conspicuous, and neutral'' is to be achieved.

The purpose of the proposed study is, in part, to determine whether the use of competing, compelling visual information about potential drug benefits interferes with viewers' processing and comprehension of risk information about drugs in DTC advertising or with their cognitive representations of the drugs. Positive visual images could influence the processing of risk-related information and the final representation of the advertised drug in multiple ways. First, compelling visuals could simply distract consumers from carefully considering and encoding the risk information. To the extent that compelling visuals cause them to attend to or to process risk information less, participants exposed to risk information with simultaneous compelling positive visuals should recall fewer risks (and perhaps fewer benefits) than do participants exposed to the risk information without the positive visuals. Second, compelling visuals may affect the way consumers think about the brand, specifically their attitudes toward the advertised brand. An attitude is simply an association between an object and a degree of positivity or negativity. Thus, the impact of varying visual displays during the presentation of audio risks may be manifested in varying attitudes toward the brand. This is important because brand attitudes may be an important determinant of future behavior toward the brand. In contexts where product information is complex, initial impressions based on more subtle processes may have as significant an impact on behavioral tendencies as impressions based upon more ''cognitively-effortful'' factual information. Because visual cues are typically easier to process than verbal information, initial attitudes for this group are likely to be greatly influenced by these cues. Under many circumstances, people rely much less on facts that they know, such as the number of risks associated with, for example, ibuprofen, and much more on general feelings they have, such as strong positivity toward a brand, such as the Advil brand of ibuprofen. Compelling visuals during the audio risk presentation of DTC broadcast advertisements have the potential to lead a consumer to form a positive opinion of a drug for no other reason than that it is presented in the same context as positive images.

Another purpose of the present study is to examine the role of textual elements in the processing of risk information. Sponsors often place