

regulations at 42 CFR Part 430, Subpart D. The overall issue in any such appeal will be whether the Florida outpatient hospital benefit is consistent with Federal requirements. Any request for such a hearing should be sent to the designated Hearing Officer. The Hearing Officer also should be notified if you request a hearing but cannot meet the timeframe expressed in this notice. Your Hearing Officer is:

Benjamin R. Cohen, Hearing Officer  
Centers for Medicare & Medicaid Services  
2520 Lord Baltimore Drive, Suite L  
Baltimore, MD 21244

If the state requests a hearing but nevertheless plans to come into compliance with the approved state plan, please submit within 30 days of the date of this letter an explanation of how the state plans to come into compliance with Federal requirements and the timeframe for doing so. If that explanation is satisfactory, we may consider postponing the timing of the scheduled hearing (which would also delay the imposition of the withholding of funds). Our goal is to ensure compliance. We are available to provide further information or assistance on the steps necessary to bring the state into compliance with its approved state plan.

Should you not request a hearing within 30 days, a notice of withholding will be sent to you and the withholding of Federal funds will begin as described above.

If you have any questions or wish to discuss this determination further, please contact:

Jackie Glaze  
Associate Regional Administrator  
Division of Medicaid and Children's Health Operations  
CMS Atlanta Regional Office  
61 Forsyth Street SW., Suite 4T20  
Atlanta, GA 30303-8909

Sincerely,

Marilynn Tavenner,  
Administrator.

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

Dated: February 20, 2014.

**Marilynn Tavenner,**

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014-04290 Filed 2-26-14; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0717]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On February 7, 2014, the Agency submitted a proposed collection of information entitled "Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaign" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0753. The approval expires on October 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 21, 2014.

**Leslie Kux,**

Assistant Commissioner for Policy.

[FR Doc. 2014-04271 Filed 2-26-14; 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; Proposed Collection; Comment Request; Prescription Drug Advertisements

**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, 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 April 28, 2014.

**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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**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 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
202.1(e)(6)—Waiver request to FDA .....	1	1	1	12	12
202.1(j)(1)—Submission of advertisement to FDA for prior approval .....	1	1	1	2	2
202.1(j)(1)(iii)—Providing a program to FDA for assuring that adverse information about the drug will be publicized .....	1	1	1	12	12
202.1(j)(4)—Voluntarily submitting the advertisement to FDA prior to publication for comment .....	113	6	678	20	13,560

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total .....					13,586

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
202.1—Advertisements prepared in accordance with § 202.1 .....	541	46.5	25,157	400	10,062,800
202.1(j)(1)—Including information about the drug's fatalities or serious damage in the advertisement .....	1	1	1	40	40
Total .....					10,062,840

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 24, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-04262 Filed 2-26-14; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration Center for Substance Abuse Prevention**

**Notice of Meeting**

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) Drug Testing Advisory Board (DTAB) will meet on March 17, 2014, from 9:00 a.m. to 4:30 p.m., and March 18, 2014, from 9:00 a.m. to 2:00 p.m. E.D.T. The DTAB will convene in both open and closed sessions on these two days.

On March 17, 2014, from 9:00 a.m. to 4:30 p.m., the meeting will be open to the public and will include updates on the previously announced DTAB recommendations, the medical review officer resources, the custody and control form, the Federal Drug-Free Workplace Programs, the National Laboratory Certification Program, and the Division of Workplace Programs-sponsored research studies. The meeting also will include drug testing updates from the Department of Transportation, the Department of Defense, the Nuclear Regulatory Commission, the Federal Drug-Free Workplace Programs, and the Drug Testing Index®.

The public is invited to attend the open session in person or to listen via web conference. Due to the limited seating space and call-in capacity, registration is requested. Public comments are welcome. To register, make arrangements to attend, obtain the web conference call-in numbers and access codes, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Advisory Committees Web site at <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx> or contact the CSAP DTAB Designated Federal Official, Dr. Janine Denis Cook (see contact information below).

On March 18, 2014, from 9:00 a.m. to 2:00 p.m., the Board will meet in closed session to discuss proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. Therefore, this meeting is closed to the public as determined by the Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(9)(B) and 5 U.S.C. App. 2, Section 10(d).

Meeting information and a roster of DTAB members may be obtained by accessing the SAMHSA Advisory Committees Web site, <http://www.nac.samhsa.gov/DTAB/meetings.aspx>, or by contacting Dr. Cook.

*Committee Name:* Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention Drug Testing Advisory Board.

*Dates/Time/Type:* March 17, 2014, from 9:00 a.m. to 4:30 p.m. E.D.T.: OPEN; March 18, 2014, from 9:00 a.m. to 2:00 p.m. E.D.T.: CLOSED.

*Place:* Sugarloaf Conference Room, SAMHSA Building, 1 Choke Cherry Road, Rockville, Maryland 20850.

*Contact:* Janine Denis Cook, Ph.D., Designated Federal Official, CSAP Drug Testing Advisory Board, 1 Choke Cherry Road, Room 7-1043, Rockville, Maryland 20857, *Telephone:* 240-276-2600, *Fax:* 240-276-2610, *Email:* [janine.cook@samhsa.hhs.gov](mailto:janine.cook@samhsa.hhs.gov).

**Cathy J. Friedman,**

*Public Health Analyst, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 2014-04291 Filed 2-26-14; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket Number FR- 5752-N-22]

**Federal Housing Administration (FHA) Healthcare Facility Documents: Documents Eligible for Electronic Submission—30-Day Notice of Information Collection**

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** On March 14, 2013, HUD published in the **Federal Register** a notice that announced that FHA's healthcare facility documents completed the notice and comment processes under the Paperwork Reduction Act of 1995 (PRA), and had been assigned a control number, 2502-0605, by the Office of Management and Budget (OMB). The assignment of a control number concluded a 10-month process through which HUD solicited