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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–09016 Filed 4–18–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child and Family Services Plan (CFSP), Annual Progress and Services Review (APSR), and Annual Budget Expenses Request and Estimated Expenditures (CFS–101).

OMB No.: 0970–0426.

Description: Under title IV–B, subparts 1 and 2, of the Social Security Act (the Act), States, Territories, and Tribes are required to submit a Child and Family Services Plan (CFSP). The CFSP lays the groundwork for a system of coordinated, integrated, and culturally relevant family services for the subsequent five years (45 CFR 1357.15(a)(1)). The CFSP outlines initiatives and activities the State, Tribe or territory will carry out in administering programs and services to promote the safety, permanency, and well-being of children and families. By June 30 of each year, States, Territories, and Tribes are also required to submit an Annual Progress and Services Report (APSR) and a financial report called the CFS–101. The APSR is a Yearly report that discusses progress made by a State, Territory or Tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains new and updated information about service needs and organizational capacities throughout the five-year plan period. The CFS–101 has three parts. Part I is an annual budget request for the upcoming fiscal year. Part II includes a summary of planned expenditures by program area for the upcoming fiscal year, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by program area, and the geographic areas served for the last complete fiscal year.

The Child and Family Services Improvement Act of 2006 amended Title IV–B, subparts 1 and 2, adding a number of requirements that affect reporting through the APSR and the CFS–101. Of particular note, the law added a provision requiring States (including Puerto Rico and the District of Columbia) to report data on caseworker visits (section 424(e) of the Act). States must provide annual data on 1) the percentage of children in foster care under the responsibility of the State who were visited on a monthly basis by the caseworker handling the case of the child; and 2) the percentage of the visits that occurred in the residence of the child. In addition, by June 30, 2008, States must set target percentages and establish strategies to meet the goal that; by October 1, 2011; at least 90 percent of the children in foster care are visited by their caseworkers on a monthly basis and that the majority of these visits occur in the residence of the child (section 424(e)(2)(A) of the Act).

Respondents: States, Territories, and Tribes must complete the CFSP, APSR, and CFS–101. Tribes and territories are exempted from the monthly caseworker visits reporting requirement of the APSR. There are approximately 180 Tribal entities that are eligible for IV–B funding. There are 52 States (including Puerto Rico and the District of Columbia) that must complete the CFSP, APSR, and CFS–101. There are a total of 232 possible respondents.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
APSR	232	1	76.58	17,766.56
CFSP	232	1	120.25	5,579.60
CFS–101, Parts I, II, and III	232	1	4.38	1,016.16
Caseworker Visits	52	1	99.33	5,165.16

Estimated Total Annual Burden Hours: 29,527 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, 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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–08959 Filed 4–18–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0373]

Agency Information Collection Activities; Proposed Collection; Comment Request; Risk and Benefit Perception Scale Development

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study, Risk and Benefit Perception Scale Development. The study is designed to test different ways of measuring consumers' benefit and risk perceptions after exposure to direct-to-consumer (DTC) prescription drug advertising.

DATES: Submit either electronic or written comments on the collection of information by June 20, 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, *PRAStaff@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 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.

Risk and Benefit Perception Scale Development—(OMB Control Number 0910-New)

FDA requires that prescription drug advertisements be balanced in their presentation of risk and benefit information. Patients receive information on drugs not only from their doctors and pharmacies, through patient labeling and FDA-mandated medication guides, but also online, on social networks and via DTC television and print advertising. Moreover, research suggests that consumers struggle with the concepts of risk and efficacy (Ref. 1) and often overestimate drug efficacy (Ref. 2). As a result, it is important for FDA to understand and accurately measure how consumers are making sense of this information and how it impacts decisions related to prescription drugs.

FDA's Office of Prescription Drug Promotion has an active research program that investigates how DTC advertising influences consumer knowledge, perceptions, and behavior. Consequently, FDA needs a pool of reliable and valid measurement items for assessing consumers' drug risk and benefit perceptions—as well as other elements of prescription drug decision making—consistently across studies. The purpose of this project is to create that measurement pool, thus increasing the rigor and efficiency of FDA's research.

Design: This research will be conducted in two stages.

Stage 1: Pretests

The purpose of the first study stage is to pretest the candidate measurement items to assess their psychometric properties and identify any measurement challenges (e.g., misinterpretation, lack of variance). We also will use the pretest to examine factors that may affect future study results and analyses (e.g., response scale midpoints, moderating variables).

We will conduct two sequential pretest waves (n = 500 per wave; n = 1,000 total) with the following target populations: (a) Individuals diagnosed with chronic pain; and (b) individuals diagnosed with hypertension. Each participant will be randomly assigned to view either a print ad or a television ad for a fictitious prescription drug indicated to treat chronic pain; or hypertension and will be asked to complete a brief online survey assessing their benefit/risk recall, benefit/risk perceptions, and attitudes toward the drug. Based on the pretest findings, we will revise and remove candidate items prior to full-scale testing. The pretest study design is outlined in Exhibit 1.

EXHIBIT 1—PRETEST STUDY DESIGN

Wave	Medical condition		
	Chronic pain	Hyper-tension	
Wave 1	n = 250	n = 250	500
Wave 2	n = 250	n = 250	500
Total	500	500	1,000

Stage 2: Iterative Tests

In the second stage, we will conduct four sequential waves of iterative testing to fully assess the measurement properties of the candidate items and create the final pool of measurements. We will conduct the first two waves with members of the target populations (hypertension and chronic pain) to refine the measurement items for those groups and the second two waves with members of the general population who do not have the target health conditions to determine if measurement reliability and validity change when the advertised drug addresses a condition that study participants do not have (n = 2,500 per wave; n = 10,000).

Each participant will be randomly assigned to view either a print or television ad for a fictitious prescription drug for hypertension or chronic pain and will be asked to complete a brief online survey assessing their benefit/risk recall, benefit/risk perceptions, and attitudes toward the drug. In the first two waves, participants will view an ad that matches the sample's medical condition (chronic pain or hypertension). In the final two waves, half of the general population sample will be exposed to the chronic pain stimuli, and half will be exposed to the high blood pressure stimuli.

The first two waves are outlined in Exhibit 2, and the final two waves are outlined in Exhibit 3.

EXHIBIT 2—ITERATIVE TESTING DESIGN; ILLNESS POPULATION SAMPLE

Chronic pain ad					Hypertension ad				
Ad type	Drug risk level	Drug benefit level		Control	Ad type	Drug risk level	Drug benefit level		Control
		High	Low				High	Low	
Wave 1									
Print	High	n = 125	n = 125	n = 125	Print	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	
Television	High	n = 125	n = 125	n = 125	Television	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	
Wave 2									
Print	High	n = 125	n = 125	n = 125	Print	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	
Television	High	n = 125	n = 125	n = 125	Television	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	

EXHIBIT 3—ITERATIVE TESTING DESIGN; GENERAL POPULATION SAMPLE

Chronic pain ad					Hypertension ad				
Ad type	Drug risk level	Drug benefit level		Control	Ad type	Drug risk level	Drug benefit level		Control
		High	Low				High	Low	
Wave 3									
Print	High	n = 125	n = 125	n = 125	Print	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	
Television	High	n = 125	n = 125	n = 125	Television	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	
Wave 4									
Print	High	n = 125	n = 125	n = 125	Print	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	
Television	High	n = 125	n = 125	n = 125	Television	High	n = 125	n = 125	n = 125
	Low	n = 125	n = 125			Low	n = 125	n = 125	

Participants and Burden Hours and General Methods

Participants will be randomly assigned to view one version of a fictitious prescription drug ad (print or television). The drug risks and benefits in each ad will be manipulated into high or low conditions, creating four different ad versions: high benefit/high risk, high benefit/low risk, low benefit/high risk, and low benefit/low risk. There also will be a control condition in which the ad does not contain any risk or benefit information (reminder ad). The fictitious prescription drugs will be modeled on real drugs used to treat the same conditions and created with the input of medical experts.

During the study, we will expose participants to one of these fictitious ads and ask them to answer a series of questions about the fictitious drug. The questions represent the candidate measures we are testing in this study, and we will examine which measures are most sensitive/accurate in capturing participants' perceptions of the advertised drug. (For example, an accurate measure should detect different perceptions in a participant who sees a high benefit/high risk ad versus a participant who sees a low benefit/low risk ad.) We have designed the study and selected sample sizes (described previously) so that we will have sufficient statistical power to detect small-to-medium sized differences between the candidate measures and the ability to refine and re-test measures to ensure their accuracy.

For both the pretests and iterative tests, the questionnaire is expected to last no more than 20 minutes (the questionnaire is available upon request). This will be a one-time (rather than annual) collection of information. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	22,000	1	22,000	0.03 (2 minutes)	660
Pretest	1,000	1	1,000	0.33 (20 minutes)	330
Main Study	10,000	1	10,000	0.33 (20 minutes)	3,300

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					4,290

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

References

1. Lipkus, I.M. ''Numeric, Verbal, and Visual Formats of Conveying Health Risks: Suggested Best Practices and Future Recommendations.'' *Medical Decision Making,* 27(5), 696–713 (2007).

2. Aikin, K.J., J.L. Swasy, and A.C. Braman. ''Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results.'' *Food and Drug Administration, Center for Drug Evaluation and Research,* 19 (2004).

Dated: April 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08957 Filed 4–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 25, 2014, from 8:30 a.m. to 3:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 206162, olaparib capsules, application submitted by AstraZeneca Pharmaceuticals LP. The proposed indication (use) for this product is as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed ovarian cancer (including fallopian tube or primary peritoneal) with germline BRCA mutation as detected by an FDA-approved test, who are in response (complete response or partial response) to platinum-based chemotherapy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 11, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 3, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 4, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs (see *Contact Person*) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08958 Filed 4–18–14; 8:45 am]

BILLING CODE 4160–01–P