

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. 2013-22996 Filed 9-20-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Personal Responsibility Education Program (PREP).

OMB No.: 0970-0380.

Description: The Patient Protection and Affordable Care Act, 2010, also known as health care reform, amended Title V of the Social Security Act (42 U.S.C. 701 *et seq.*) as amended by sections 2951 and 2952(c), by adding section 513, authorizing the Personal Responsibility Education Program (PREP). The President signed into law the Patient Protection and Affordable Care Act on March 23, 2010, Public Law 111-148, which added the new PREP formula grant program. The purpose of this program is to educate adolescents

on both abstinence and contraception to prevent pregnancy and sexually transmitted infections (STIs); and at least three adulthood preparation subjects. The Personal Responsibility Education grant program funding is available for fiscal years 2010 through 2014. Pursuant to monitoring these state programs, grantees submit a semiannual report on their performance.

A request is being made to solicit comments from the public on paperwork reduction as it relates to ACYF's receipt of the following document from applicants and awardees:

Performance Progress Report

Respondents: 50 States and 9 Territories, to include, District of Columbia, Puerto Rico, Virgin Islands, Guam, American Samoa, Northern Mariana Islands, the Federated States of Micronesia, the Marshall Islands and Palau

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Performance Progress Reports	59	2	16	1,888

Estimated Total Annual Burden Hours: 1,888.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0985]

Complex Issues in Developing Drug and Biological Products for Rare Diseases; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled "Complex Issues in Developing Drug and Biological Products for Rare Diseases." The purpose of the public workshop is twofold: To discuss complex issues in clinical trials for developing drug and biological products ("drugs") for rare

diseases, including endpoint development and selection, use of surrogate endpoints and the accelerated approval pathway, clinical trial design, conduct and analysis, safety considerations, and dose selection; and to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases. FDA is seeking input on these topics from academic, clinical, and treating communities; patients and advocacy groups; industry; and governmental agencies. Input from this public workshop will help develop a strategic plan to encourage and accelerate the development of new therapies for rare diseases.

Date and Time: The public workshop will be held on January 6, 2014, from 8 a.m. to 5 p.m. and on January 7, 2014, from 8 a.m. to 4:45 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://>

www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: Tomeka Arnett, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6331, Silver Spring, MD 20993-0002, 301-796-2500, FAX: 301-847-3529, email: Tomeka.Arnett@fda.hhs.gov.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the public workshop must register online by December 20, 2013. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. Seating will be available on a first-come, first-served basis.

If you need special accommodations due to a disability, please contact Tomeka Arnett (see *Contact Person*) no later than 7 days in advance.

To register for the public workshop, please visit FDA's Drugs News & Events—Meetings, Conferences & Workshops calendar at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Tomeka Arnett to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast may visit FDA's Drugs News & Events—Meetings, Conferences & Workshops calendar at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm>. (Select this public workshop from the posted events list.) Select <https://collaboration.fda.gov/drugbiord/> to view the Webcast. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain information about

complex issues in clinical trials for developing drugs for rare diseases and to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop. The deadline for submitting comments regarding this public workshop is March 10, 2014.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as outlined in section II, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

The Orphan Drug Act of 1983 (the Orphan Drug Act) (Pub. L. 97-414), as amended, defines a “rare disease or condition” to include those that affect less than 200,000 persons in the United States. This definition is codified in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2)). The Orphan Drug Act provides incentives to reduce the cost and increase the potential reward for developing products for small numbers of patients; however, it does not alter the statutory standards for marketing approval. To gain approval, all drugs must demonstrate substantial evidence of effectiveness, safety, and product quality for the treatment of the condition in the identified patient population. FDA acknowledges that

certain aspects of drug development for rare diseases are challenging, and U.S. regulations allow for flexibility and scientific judgment in applying approval standards and in determining the kind and quantity of data required for a particular drug to meet the statutory standards.

This public workshop is being held in response to section 510—Pediatric rare diseases of the Food and Drug Administration Safety and Innovation Act (Pub. L. 122-144) (125 Stat. 1050), whereby FDA is required to hold at least one public meeting to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases. Additionally, as stated in section IX.E—Enhancing Drug Regulatory Science and Expediting Drug Development, Advancing Development of Drugs for Rare Diseases of the Prescription Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017 (available at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>), FDA will conduct a public meeting to discuss complex issues in clinical trials for studying drugs for rare diseases.

This public workshop is being held in conjunction with FDA's Center for Devices and Radiological Health and Office of Orphan Products Development public workshop entitled “Complex Issues in Developing Medical Devices for Pediatric Patients Affected by Rare Diseases,” which will be held on January 8, 2014, from 8 a.m. to 5 p.m., announced in a separate notice publishing elsewhere in this issue of the **Federal Register**.

II. Topics for Discussion at the Public Workshop

FDA is announcing a public workshop regarding complex issues in clinical trials for developing drugs for rare diseases and to discuss ways to encourage and accelerate the development of new therapies for pediatric rare diseases. The purpose of this public workshop is to seek broad input from rare disease experts and stakeholders, including industry; academic and clinical experts; patients and advocates and governmental agencies to address complex issues in rare disease product development.

Topics for discussion on day 1 include: (1) Complex issues for endpoints, including endpoint selection, use of surrogate endpoints and the accelerated approval pathway, clinical significance of primary endpoints, and development of patient-reported outcome instruments; (2)

complex issues for trial design conduct and analysis; (3) development of translational and regulatory science to support rare disease drug development; and (4) safety and dosing considerations, including safety exposures and assessment of dose selection.

Topics for discussion on day 2 include: (1) Collaborative research networks for pediatric rare diseases; (2) safety considerations for pediatric rare diseases; (3) pediatric rare cancers; and (4) development of gene therapies for rare pediatric disorders. Discussions will help develop a report that includes a strategic plan to encourage and accelerate the development of new therapies for pediatric rare diseases.

FDA encourages individuals, patients, advocates, industry, consumer groups, health care professionals, researchers and other interested persons to attend this public workshop.

Dated: September 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1041]

Fibromyalgia Public Meeting on Patient-Focused Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for fibromyalgia. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of fibromyalgia on daily life as well as the available therapies for fibromyalgia.

DATES: The public meeting will be held on December 10, 2013, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by November 27, 2013. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit electronic or written comments by February 10, 2013.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, in Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

Submit electronic comments to www.regulations.gov. Submit written comments 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.

FDA will post the agenda approximately 5 days before the meeting at: <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm363203.htm>.

FOR FURTHER INFORMATION CONTACT:

Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1199, Silver Spring, MD 20993, 301-796-5003, FAX: 301-847-8443, *email:* Graham.Thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected fibromyalgia as the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (FDASIA) (Pub. L. 112-144). The full set of performance commitments is available on the FDA Web site at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

FDA has committed to obtain the patient perspective in twenty disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients'

perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 08441) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FY) 2013-2015, the first 3 years of the 5-year PDUFA V timeframe. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency obtained public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 23454, and through a public meeting held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. By the end of FY 2015, FDA will initiate another public process for determining the disease areas for FY 2016-2017. More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on symptoms of fibromyalgia that matter most to patients and on current approaches to treating fibromyalgia. Fibromyalgia is a chronic disorder characterized by widespread musculoskeletal pain and tenderness in multiple tender points and may be accompanied by fatigue, sleep disturbances, irritable bowel syndrome, headache, and mood disorders. While there is currently no definitive cure, treatments for fibromyalgia include medications and lifestyle changes with emphasis on minimizing symptoms and improving general health and daily function. FDA is interested in obtaining a better understanding of fibromyalgia patients' perspectives on the severity of the disease and the available therapies used to treat fibromyalgia and its symptoms.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from