SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–16–043

93.103

A. Background

The OOPD was created to identify and promote the development of orphan products. Orphan products are drugs, biologics, medical devices, and medical foods that are indicated for a rare disease or condition. The term ''rare disease or condition'' is defined in section 528 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ee). FDA generally considers drugs, devices, and medical foods potentially eligible for grants under the OOPD grant program if they are indicated for a disease or condition that has a prevalence, not incidence, of fewer than 200,000 people in the United States. Diagnostics and vaccines are considered potentially eligible for such grants only if the U.S. population to whom they will be administered is fewer than 200,000 people in the United States per year.

The natural history of a disease is the natural course of a disease from the time immediately prior to its inception, progressing through its pre-symptomatic phase and different clinical stages to the point where the disease has ended without external intervention. Natural history studies track the course of disease over time, identifying demographic, genetic, environmental, and other variables that correlate with its development and outcomes in the absence of treatment. Thorough understanding of disease natural history is the foundation upon which a clinical development program for drugs, biologics, medical foods or medical devices is built.

Rare diseases, as defined in the United States Orphan Drug Act (ODA) (Pub. L. 97–414), are diseases or conditions with a prevalence of fewer than 200,000 persons in the United States. Though individually rare, together there are approximately 30 million Americans affected by 7,000 known rare diseases. Unlike common diseases, there is little existing knowledge on the natural history of most rare diseases, which makes natural history studies of particular importance for rare diseases product development. In January 2014, the FDA organized a Public Workshop on Complex Issues in Developing Drugs for Rare Diseases. During the workshop, the lack of natural history studies was reconfirmed by all stakeholders (patients, industry, researchers and the FDA) as one of the most common and urgent issues that hinder treatment development for rare diseases. The need for natural history studies was also emphasized in the recently published (August 17, 2015) draft FDA Guidance for Industry, ''Rare Diseases: Common Issues in Drug Development,'' available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM458485.pdf.*

B. Research Objectives

The objective of FDA's Orphan Products Natural History Grants Program is to support studies that characterize the natural history of rare diseases/conditions, identify genotypic and phenotypic subpopulations, and develop and/or validate clinical outcome measures, biomarkers and/or companion diagnostics. The ultimate goal of these natural history studies is to support clinical development of products for use in serious rare diseases or conditions where no current therapy exists or where the proposed product will be superior to the existing therapy. FDA provides grants for natural history studies that will either assist or substantially contribute to market approval of these products. Applicants must include in the application's Background and Significance section documentation to support that the estimated prevalence of the orphan disease or condition in the United States is less than 200,000 (or in the case of a vaccine or diagnostic, information to support that the product will be administered to fewer than 200,000 people in the United States per year), and an explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

C. Eligibility Information

The grants are available to any foreign or domestic, public or private, for-profit or nonprofit entity (including State and local units of government). Federal Agencies may not apply.

II. Award Information/Funds Available

A. Award Amount

Of the estimated FY 2017 funding ($17.7 million), approximately $2 million will fund 2 to 5 new awards, subject to availability of funds. Prospective Natural History Studies are eligible for grants of up to $400,000 per year for up to 5 years. Retrospective Natural History Studies or Surveys are eligible for grants of up to $150,000 per year for up to 2 years. Please note that the dollar limitation will apply to total costs (direct plus indirect). Budgets for each year of requested support may not exceed the $150,000 or $400,000 total cost limit, whichever is applicable.

B. Length of Support

The length of support will depend on the nature of the study. For those studies with an expected duration of more than 1 year, all future years of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year; (2) compliance with regulatory requirements as applicable; and (3) availability of Federal funds.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://grants.nih.gov/grants/guide.* For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM) (formerly Central Contractor Registration (CCR))
- Step 3: Obtain Username & Password on Grants.gov
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit electronic applications to: *http://www.grants.gov.*

Dated: April 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10398 Filed 5–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Quantitative Assessment of Assumptions To Support Extrapolation of Efficacy in Pediatrics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (CERSI), is announcing a public workshop entitled ''Quantitative Assessment of Assumptions to Support Extrapolation of Efficacy in Pediatrics.'' The objective of the workshop is to discuss quantitative and qualitative approaches for verifying assumptions pertaining to disease and therapeutic response similarity between adults and children. The workshop will also provide a forum for discussion on the use of modeling and simulation for systematic assessment of extrapolation assumptions.

DATES: The public workshop will be held on June 1, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: 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. 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.*

FOR FURTHER INFORMATION CONTACT: Audrey Thomas, Office of Regulatory Science and Innovation, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4220, Silver Spring, MD 20993–0002, 301–796–3520, *Audrey.Thomas@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide an opportunity for relevant stakeholders, including clinicians, academia, industry, and FDA to discuss systematic assessment of data needed to support extrapolation of efficacy in pediatric product development. Specifically, the workshop will include: (1) Presentations on approaches for assessing disease and therapeutic response similarity between adults and pediatrics, and (2) discussion of alternative approaches to the assessment of extrapolation assumptions in pediatric product development, including the use of clinical trial simulation and Bayesian approaches. Examples in partial onset seizures, inflammatory bowel diseases, and polyarticular juvenile idiopathic arthritis will be presented and discussed.

FDA has verified the Web site addresses in this document, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**

Agenda: The agenda is located at *www.pharmacy.umaryland.edu/PedsExtrapolation.*

Registration: There is a registration fee to attend this public workshop in person. Seats are limited and registration will be on a first-come, first-served basis. To register, please complete registration online at *www.pharmacy.umaryland.edu/PedsExtrapolation.* There will be no onsite registration. The costs of registration, to attend in person, for the different categories of attendees are as follows:

Category	Cost
Industry Representative	$50
Nonprofit Organization and Academic other than University of Maryland	50
University of Maryland, College Park and Baltimore	0
Federal Government	0

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. There is no registration fee for access to the workshop via the Webcast, but registration is still required. Information regarding access to the Webcast link is available at *www.pharmacy.umaryland.edu/PedsExtrapolation.* 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.* To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview.*

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations while at FDA's White Oak Campus due to a disability, please contact Shari Solomon at *Shari.Solomon@fda.hhs.gov* at least 7 days in advance.

Dated: April 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–10397 Filed 5–3–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1170]

Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in all phases of development of direct-acting antiviral (DAA) drugs for the treatment of chronic hepatitis C. This draft guidance revises the draft guidance of the same name that was issued on October 23, 2013.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the