

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0724]

Documents to Support Submission of an Electronic Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the following final versions of documents that support making regulatory submissions in electronic format using the electronic Common Technical Document (eCTD) specifications: “The eCTD Backbone Files Specification for Module 1, version 2.0” (which includes the U.S. regional document type definition (DTD), version 3.0) and “Comprehensive Table of Contents Headings and Hierarchy, version 2.0.” Supporting technical files are also being made available on the Agency Web site. These documents represent FDA’s major updates to Module 1 of the eCTD, which contains regional information. FDA is not prepared at present to accept submissions utilizing this new version because eCTD software vendors need time to update their software to accommodate this information and because its use will require software

upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.0 by September 2013, but this is not a firm date and we will give 30 days advance notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm 2201, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT:

Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm 1161, Silver Spring, MD 20993, email: Esub@fda.hhs.gov; or Mary Padgett, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-0373, email: mary.padgett@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA’s Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the administrative portion of the eCTD (Module 1) to reflect regulatory changes, to provide clarification of business rules for submission processing and review, to refine the characterization of promotional marketing and advertising material, and to facilitate automated processing of submissions. In preparation for the Module 1 update, FDA made available draft technical documentation for public comment in a **Federal Register** notice dated October 26, 2011 (Docket No.

FDA-2011-N-0724). After considering comments submitted, FDA revised the draft documentation and is making available final versions of the following documents:

- “The eCTD Backbone Files Specification for Module 1, version 2.0,” which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER. It should be used in conjunction with the guidance for industry “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications,” which can be found online (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072349.pdf>), and which will be revised as part of the implementation of the updated eCTD backbone files specification.
- “Comprehensive Table of Contents Headings and Hierarchy, version 2.0,” which reflects updated headings that are specified in the draft document entitled “The eCTD Backbone Files Specification for Module 1, version 2.0,” as well as mappings to regulations and legislation.

Supporting technical files are also being made available on the Agency Web site. The documents include changes that:

- Allow submission of promotional label and advertising materials to CDER in eCTD format;
- Provide for processing of grouped submissions (e.g., a supplement that can be applied to more than one new drug application or biologics license application);
- Provide detailed contact information so that companies can specify points of contact to discuss technical matters that may arise with a submission;
- Clarify headings;
- Use attributes in place of certain headings to provide flexibility for future changes without revising the specification itself.

FDA is not prepared at present to accept submissions utilizing this new version because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.0 by September 2013, but this is not a firm date and we will give 30 days advance notice to industry.

II. Electronic Access

Persons with access to the Internet may obtain the documents at either <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm>, <http://www.regulations.gov>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: July 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-19087 Filed 8-3-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0011]

Clinical Studies of Safety and Effectiveness of Orphan Products Research Project Grant (R01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of FDA's Office of Orphan Products Development (OPD) grant program. The goal of FDA's OPD grant program is to support the clinical development of products for use in 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 clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's Background and Significance section documentation to support the assertion that the product to be studied meets the statutory criteria to qualify for the grant and an explanation of how the proposed study will either help support product approval or provide essential data needed for product development.

DATES: Important dates are as follows:

1. The application due dates are February 6, 2013; February 5, 2014. The resubmission due dates are October 15, 2013; October 15, 2014.
2. The anticipated start dates are November 2013; November 2014.
3. The opening date is December 6, 2013.
4. The expiration date is February 6, 2014; October 16, 2014 (resubmission).

For Further Information and Additional Requirements Contact: Katherine Needleman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993-0002, Phone: 301-796-8660, Email: katherine.needleman@fda.hhs.gov; or Vieda Hubbard, Office of Acquisitions & Grant Services, 5630 Fishers Lane, rm. 2034, Rockville, MD 20857, Phone: 301-827-7177, Email: vieda.hubbard@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://grants.nih.gov/grants/guide> (select the "Request for Applications" link), <http://www.grants.gov> (see "For Applicants" section), and <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/WhomtoContactaboutOrphanProductDevelopment/ucm134580.htm>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-13-001
93.103

A. Background

The OPD 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 OPD 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.

B. Research Objectives

The goal of FDA's OPD grant program is to support the clinical development of products for use in 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 clinical studies on safety and/or effectiveness that will either result in, or substantially contribute to, market approval of these products. Applicants must include in the application's Background and

Significance section documentation to support the assertion that the product to be studied meets the statutory criteria to qualify for the grant 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 that are not part of the Department of Health and Human Services (HHS) may apply. Agencies that are part of HHS may not apply. For-profit entities must commit to excluding fees or profit in their request for support to receive grant awards. Organizations that engage in lobbying activities, as described in section 501(c)(4) of the Internal Revenue Code of 1968, are not eligible to receive grant awards.

II. Award Information/Funds Available

A. Award Amount

Of the estimated FY 2014 funding (\$14.1 million), approximately \$10 million will fund noncompeting continuation awards, and approximately \$4.1 million will fund 5 to 10 new awards, subject to availability of funds. It is anticipated that funding for the number of noncompeting continuation awards and new awards in FY 2015 will be similar to FY 2014. Phase 1 studies are eligible for grants of up to \$200,000 per year for up to 3 years. Phase 2 and 3 studies are eligible for grants of up to \$400,000 per year for up to 4 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 \$200,000 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, a second, third, or fourth year of noncompetitive continuation of support will depend on the following factors: (1) Performance during the preceding year; (2) compliance with regulatory requirements of IND/investigational device exemption (IDE); 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