4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0313]

Meetings with the Office of Orphan Products Development; Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry, researchers, patient groups, and FDA staff entitled "Meetings with the Office of Orphan Products Development." This guidance provides recommendations to industry, researchers, patient groups, and other stakeholders (collectively referred to as "stakeholders") interested in requesting a meeting with FDA's Office of Orphan Products Development (OOPD) on issues related to orphan drug designation requests, humanitarian use device (HUD) designation requests, rare pediatric disease designation requests, funding opportunities through the Orphan Products Grants Program and the Pediatric Device Consortia Grants Program, and orphan product patient-related topics of concern. This guidance document is intended to assist these groups with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD. This guidance finalizes the draft guidance of the same title dated April 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Orphan Products Development (OOPD), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5295, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OOPD at 301-796-8660. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James D. Bona, Office of Orphan Products Development (OOPD), Food and Drug Administration, Bldg. 32, rm. 5204, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8673, email: james.bona@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, researchers, patient groups, and FDA staff entitled "Meetings with the Office of Orphan Products Development." Each year, OOPD staff participates in meetings with stakeholders who seek guidance or clarification relating to orphan drug or HUD designation requests, OOPD grant programs, or other rare disease issues. These meetings can be "informal" or "formal" and help build a common understanding on FDA's thoughts on orphan products, which may include drugs, biological products, devices, or medical foods for a rare disease or condition. These meetings may represent critical points in the orphan product development process and may even have an impact on the eventual availability of products for patients with rare diseases and conditions. It

is important that these meetings be scheduled within a reasonable time, conducted effectively, and documented where appropriate. This guidance is intended to provide consistent procedures to promote well-managed meetings between OOPD and stakeholders.

Topics addressed in this guidance include: (1) Clarification of what constitutes an "informal" or "formal" meeting, (2) program areas within OOPD that may be affected by this draft guidance, (3) procedures for requesting and scheduling meetings with OOPD, (4) description of what constitutes a meeting package, and (5) procedures for the conduct and documentation of meetings with OOPD.

In the Federal Register of April 9, 2014 (79 FR 19623), FDA issued, for public comment, "Draft Guidance for Industry, Researchers, Patient Groups, and Food and Drug Administration Staff on Meetings with the Office of Orphan Products Development." The Agency issued this draft guidance to assist stakeholders with requesting, preparing, scheduling, conducting, and documenting meetings with OOPD. In particular, the draft guidance provided clarification on what constitutes an "informal" or "formal" meeting, program areas within OOPD that may be affected by the guidance, procedures for requesting and scheduling meetings with OOPD, description of what constitutes a meeting package, and procedures for the conduct and documentation of meetings.

We received several comments on the draft guidance. Most comments appreciated the clarification and explanation provided by the draft guidance. Some comments made recommendations to improve clarity.

FDA is issuing the draft guidance in final form with minor revisions to improve clarity. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on meetings with OOPD. It

does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in this guidance were approved under OMB control numbers 0910-0167, 0910-0332, and 0910-0787.

III. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). 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. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/RegulatoryInformation/Guidances/default.htm or at http://www.regulations.gov.

Dated: July 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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