This document is scheduled to be published in the
Federal Register on 05/01/2014 and available online at
http://federalregister.gov/a/2014-09897, and on **FDsys.gov**

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0458]

Providing Information about Pediatric Uses of Medical Devices; Guidance for Industry 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 the guidance entitled "Providing Information about Pediatric Uses of Medical Devices." FDA is issuing this guidance document to describe how to compile and submit the readily available pediatric use information required under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Providing Information about Pediatric Uses of Medical Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), 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 request.

Submit electronic comments on the guidance to http://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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1651, Silver Spring, MD 20993-0002, 301-796-6563; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

I. Background

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA)[1] (Pub. L. 110-85) amended the FD&C Act by adding, among other things, a new section 515A (21 U.S.C. 360e-1) of the FD&C Act. Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications to include, if readily available: (1) A description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure and (2) the number of affected pediatric patients.

The purpose of this guidance document is to describe the type of information that FDA believes is readily-available to the applicant, and the information FDA believes should be included in a submission to meet the requirements of section 515A(a) of the FD&C Act. The draft version of this guidance was issued on February 19, 2013 (78 FR 11654).

[1] Title III of FDAAA, which includes new section 515A, is also known as the Pediatric Medical Device Safety and Improvement Act of 2007.

II. Significance of Guidance

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 the requirements relating to the submission of information on pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov or from CBER at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. Persons unable to download an electronic copy of "Providing Information about Pediatric Uses of Medical Devices," may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1801 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

On January 9, 2014, the Agency submitted a proposed collection of information entitled "Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug and Cosmetic Act" to OMB for review and clearance under 44 U.S.C. 3507.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0762. The approval expires on March 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 814, subpart B have been approved under OMB control number 0910-0231 and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332.

V. Comments

Interested persons may submit either written 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.

Dated: April 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-09897 Filed 04/30/2014 at 8:45 am; Publication Date: 05/01/2014]