4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0814]

Draft Guidance for Industry on Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans." This draft guidance is intended to provide information to industry on how to submit initial and amended pediatric study plans (PSPs) as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA).

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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.

FOR FURTHER INFORMATION CONTACT: Rosemary Addy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6312, Silver Spring, MD 20993-0002, 301-796-1640; 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans." The purpose of this draft guidance is to assist sponsors in the submission of an initial PSP and any amendments to the PSP. Specifically, this guidance addresses FDA's current thinking regarding implementation of the requirement for sponsors to submit an initial PSP under section 505B of the FD&C Act as amended by FDASIA (Public Law 112-144, 126 Stat. 993 (enacted July 9, 2012)).

This draft guidance addresses topics related to the submission of an initial PSP and any amendments to the PSP, including who must submit an initial PSP, when a PSP must be submitted, what is expected to be included in an initial PSP, and what is expected to be included in a requested amendment to an initial PSP. The guidance also includes a template that should be used for submission of an initial PSP.

This draft guidance does not contain a discussion of general requirements for pediatric drug development under the Pediatric Research Equity Act. That topic is addressed in the draft guidance for industry entitled "How to Comply With the Pediatric Research Equity Act."[1]

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the content of and process for submitting initial PSPs and amended PSPs. 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. The Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collections of information referenced in this draft guidance that are related to the burden on the submission of investigational new drug applications are covered under 21 CFR part 312, including plans for pediatric studies under 21 CFR 312.47(b)(1)(iv) and waiver requests under 21 CFR 312.10, and have been approved under OMB

[1] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA Drugs guidance Web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

control number 0910-0014. The collections of information referenced in this draft guidance that are related to the burden on the submission of new drug applications are covered under 21 CFR part 314, including pediatric use information under 21 CFR 314.50(d)(7) and waiver requests under 21 CFR 314.90, and have been approved under OMB control number 0910-0001. The collections of information referenced in this draft guidance that are related to the burden on the submission of biologic license applications are covered under 21 CFR part 601, including pediatric use information and waiver requests under 21 CFR 601.27, and have been approved under OMB control number 0910-0338.

Sponsors are already required to submit plans for pediatric studies and often provide the information outlined in this guidance pursuant to the regulations noted above. The new FDASIA provisions primarily serve to establish a more precise timeline for the submission of that information; however, some of the information may be considered a new collection of information. Federal law at 44 U.S.C. 3506(c)(2)(A) requires Federal Agencies to publish a 60-day notice in the Federal Register for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice of the proposed collection of information in a future issue of the Federal Register for any information collections recommended in this guidance that may be considered new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

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 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: July 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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