4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1174]

Special Protocol Assessment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Special Protocol Assessment." This draft guidance provides information about the procedures and general policies adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for special protocol assessment (SPA). This draft guidance is intended to improve the quality of Requests for SPAs and accompanying submission materials, and the quality of the resulting interaction between sponsors and FDA. This draft guidance revises the guidance for industry entitled "Special Protocol Assessment" issued May 17, 2002.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1174 for "Special Protocol Assessment; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, 10001 New Hampshire Ave., Hillandale Building., 4th Floor, Silver Spring, MD 20993-0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. 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.

FOR FURTHER INFORMATION CONTACT: Amalia Himaya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6439, Silver Spring, MD 20993-0002, 301-796-0700; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Special Protocol Assessment." SPA is a process by which sponsors may request to meet with FDA to reach agreement on the design and size of certain trials, clinical studies, or animal trials to determine if they adequately address scientific and regulatory requirements. After completing the SPA review, FDA issues a letter including an assessment of the protocol, agreement or nonagreement with the proposed protocol, and answers to the sponsor's relevant questions. Section 119 of the Food and Drug Administration Modernization Act of 1997 amended section 505(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)) and directed FDA to meet with sponsors who request to meet, provided certain conditions are met, to reach agreement on the design and size of the well-controlled clinical trials intended to form the primary basis for a demonstration of effectiveness in a marketing application submitted under section 505(b) of the FD&C Act or section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262). These provisions subsequently were amended in section 7002(d)(1) of the Biologics Price Competition and Innovation Act of 2009 to include any necessary clinical study or studies for biosimilar biological product applications under section 351(k) of the PHS Act. In 2013, the Pandemic and All Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) further amended the SPA provisions to provide for SPA agreements regarding animal and associated clinical trials conducted in support of applications for products developed under 21 CFR part 314 subpart I, and 21 CFR part 601 subpart H (the animal rule). Such marketing applications include new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements to approved NDAs and BLAs.

In conjunction with the Prescription Drug User Fee Amendments of 2012 (PDUFA V), enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), and with the Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of FDASIA, FDA agreed to specific performance goals (PDUFA V goals and BsUFA goals, respectively) for SPA. Per section 505(b)(5)(B) of the FD&C Act, the PDUFA V goals, and the BsUFA goals, the following protocols are eligible for SPA: (1) Animal carcinogenicity protocols; (2) drug substance and drug product stability protocols; (3) animal efficacy protocols for studies intended to provide primary evidence of effectiveness required for approval or for licensure for products developed under the animal rule; (4) protocols for clinical trials or studies intended to form the primary basis of an efficacy claim; and (5) protocols for clinical studies necessary to prove biosimilarity and/or interchangeability.

This draft guidance revises the guidance of the same name issued in May 2002. After it has been finalized, this guidance will replace the May 2002 guidance. Significant changes from the 2002 version include the following: (1) Clarifying which protocols are eligible for SPA; (2) adding animal rule efficacy protocols intended to support approval under part 314 subpart I, and part 601 subpart H, for drugs and biological products, respectively; (3) adding protocols intended to support approval of a biosimilar biological product; (4) providing greater detail about the content of an SPA submission; and (5) clarifying the process for rescinding an SPA agreement. FDA seeks comments to aid in finalizing this draft guidance.

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 current thinking of FDA on the procedural aspects of SPA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it

satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information 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 referred to in the guidance entitled "Special Protocol Assessment" have been approved under OMB control number 0910-0470. The collections of information for FDA Form 1571 have been approved under OMB control number 0910-0014.

III. 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: April 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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