4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1995-D-0288 (formerly Docket No. 95D-0052)]

Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled "Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; Draft Guidance for Industry." The draft guidance is intended to assist applicants and manufacturers of certain licensed biological products in determining which reporting category is appropriate for a change in chemistry, manufacturing, and controls (CMC) information to an approved biologics license application (BLA). The draft guidance provides applicants and manufacturers general and administrative information on reporting and evaluating changes and recommendations for reporting categories based on a tiered-reporting system for specific changes. The draft guidance, when finalized, is intended to supersede the document entitled "Guidance for Industry: Changes to an Approved Application: Biological Products" dated July 1997 (July 1997 guidance).

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-1995-D-0288 (formerly Docket No. 95D-0052) for "Chemistry, Manufacturing, and Controls Changes to an Approved Application: Biological Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 Dockets Management Staff. 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: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica T. Walker, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products;

Draft Guidance for Industry." The draft guidance, when finalized, is intended to assist applicants and manufacturers of licensed biological products in determining which reporting category is appropriate for a change in CMC to an approved BLA as specified in 21 CFR 601.12. The draft guidance provides applicants and manufacturers general and administrative information on reporting and evaluating changes and recommendations for reporting categories based on a tiered-reporting system for specific changes under § 601.12.

FDA issued the July 1997 guidance (62 FR 39904; July 24, 1997) to assist applicants in determining which reporting mechanism is appropriate for reporting a change to an approved application to reduce the burden on manufacturers when reporting changes and to facilitate the approval process of the change being made. We are updating the July 1997 guidance to accommodate advances in manufacturing and testing technology and to clarify the FDA's current thinking on assessing reportable changes. The updated guidance applies to certain biological products licensed under the Public Health Service Act (PHS Act), including in vitro diagnostics licensed under BLAs. This draft guidance applies to all manufacturing locations, including contract locations. The following biological products are not within the scope of this guidance: whole blood, blood components, source plasma, and source leukocytes. This draft guidance also does not apply to human cells, tissues, and cellular and tissue-based products regulated solely under section 361 of the PHS Act (42 U.S.C. 264), as described in 21 CFR part 1271; specified biotechnology and specified synthetic biological products; and biosimilar biological products subject to licensure under section 351(k) of the PHS Act. The draft guidance, when finalized, is intended to supersede the July 1997 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 "Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products." 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information 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 21 CFR part 210 and 21 CFR part 211 have been approved under OMB control number 0910-0139; the collections of information in 21 CFR 601.12 have been approved under OMB control numbers 0910-0338, and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: December 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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