



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0643]

Labeling for Biosimilar Products; 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 final guidance for industry entitled “Labeling for Biosimilar Products.” This guidance is intended to help applicants develop draft labeling for proposed biosimilar products. The recommendations for prescription drug labeling in this guidance pertain only to the prescribing information (commonly referred to as the package insert), except for certain recommendations pertaining to FDA-approved patient labeling (e.g., Patient Information, Medication Guide, and Instructions for Use). This guidance provides an overview of FDA’s recommendations for labeling for biosimilar products. This guidance finalizes the draft guidance issued on April 4, 2016.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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-2016-D-0643 for "Labeling for Biosimilar Products; Guidance for Industry; Availability." 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 <https://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 this 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 the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6522, Silver Spring, MD 20993, 301-796-1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Labeling for Biosimilar Products.” The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148) on March 23, 2010, created an abbreviated licensure pathway for biological products demonstrated to be biosimilar to or interchangeable with an FDA-licensed reference product.

Section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or supplement for a proposed interchangeable product. Under section 351(k) of the PHS Act, a proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure, and this is reflected in the approach to biosimilar product labeling.

In this guidance, FDA outlines its recommendations for biosimilar product labeling. A demonstration of biosimilarity means, among other things, that FDA has determined that there are no clinically meaningful differences between the proposed product and the reference product in terms of safety, purity, and potency. Accordingly, biosimilar applicants should incorporate relevant data and information from the reference product labeling, with appropriate modifications as recommended in the guidance.

This guidance finalizes the draft guidance issued on April 4, 2016. Changes made to the guidance took into consideration the comments received, as well as requests regarding the requirements for and/or contents of biosimilar labeling made in the following citizen petitions: FDA-2015-P-2000 (submitted by AbbVie, Inc.), FDA-2015-P-4529 (submitted by a group of institutional investors including the United Auto Workers (UAW) Retiree Medical Benefits Trust), and FDA-2015-P-0776 (submitted by the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization) (these citizen petitions are available at <https://www.regulations.gov>). Editorial changes were made primarily for clarification.

In the *Federal Register* of April 4, 2016 (81 FR 19194), FDA announced the availability of the draft guidance for industry “Labeling for Biosimilar Products.” FDA requested comment

on whether FDA-approved patient labeling (e.g., Patient Information, Medication Guide, and Instructions for Use) should include a biosimilarity statement similar to the statement described in section IV.C.1 of the draft guidance. Several comments agreed with inclusion of the biosimilarity statement; one comment disagreed. FDA considered the comments received, but decided not to recommend inclusion of a biosimilarity statement in FDA-approved patient labeling at this time.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Labeling for Biosimilar 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 guidance 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 for the submission of a biologics license application under section 351(k) of the PHS Act have been approved under OMB control number 0910-0719; the collections of information in 21 CFR 201.56 and 201.57 for the submission of labeling have been approved under OMB control number 0910-0572; the collections of information in 21 CFR part 208 for Medication Guides have been approved under OMB control number 0910-0393; the collections of information in 21 CFR 312.47 for meetings with FDA have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 600 for the submission of adverse experience reporting for licensed biological products and general records

have been approved under OMB control number 0910-0308; and the collections of information in 21 CFR part 601 for the submission of labeling in a biologics license application or supplement to a biologics license application have been approved under OMB control number 0910-0338.

III. Electronic Access

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

Dated: July 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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