4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1543]

Nonproprietary Naming of Biological Products: Update; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled "Nonproprietary Naming of Biological Products: Update." This draft guidance describes FDA's current thinking on nonproprietary names of biological products licensed under the Public Health Service Act (PHS Act) that do not include an FDA-designated suffix. Specifically, the nonproprietary names of these products need not be revised to accomplish the objectives of the naming convention described in the final guidance for industry, "Nonproprietary Naming of Biological Products," dated January 2017. Similarly, FDA does not intend to apply the naming convention described in the final guidance for industry, "Nonproprietary Naming of Biological Products," to biological products that are the subject of an approved application under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as of March 23, 2020, when such an application is deemed to be a biologics license application (BLA) under the PHS Act (transition biological products). FDA is also reconsidering whether vaccines should be within the scope of the naming convention. In addition, the draft guidance describes FDA's current thinking on the appropriate suffix format for the nonproprietary name of an interchangeable biological product licensed under the PHS Act. Based on the comments

received in the docket, we intend to revise the final guidance, "Nonproprietary Naming of Biological Products," dated January 2017 and to amend sections in that document regarding the subjects addressed in this draft guidance.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the revisions of the final version of the guidance.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-2013-D-1543 for "Nonproprietary Naming of Biological Products: Update." 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 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 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 draft 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 20993-0002, 301-796-1042; or Stephen Ripley, 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 guidance for industry entitled "Nonproprietary Naming of Biological Products: Update." This draft guidance describes FDA's current thinking on nonproprietary names of biological products licensed under section 351 of the PHS Act (42 U.S.C. 262) that do not include an FDA-designated suffix. Specifically, the nonproprietary names of these products need not be revised in order to accomplish the objectives of the naming convention described in the final guidance for industry, "Nonproprietary Naming of Biological Products" (Naming Guidance). Similarly, FDA does not intend to apply the naming convention described in the Naming Guidance to biological products that are the subject of an approved application under section 505 of the FD&C Act (21 U.S.C. 355) as of March 23, 2020, when such an application is deemed to be a BLA under section 351 of the PHS Act (section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009) (transition biological products). FDA is also reconsidering whether vaccines should be within the scope of the naming convention.

In addition, this draft guidance describes FDA's current thinking on the appropriate suffix format for the nonproprietary name of an interchangeable biological product licensed under section 351(k) of the PHS Act. For each interchangeable product, FDA intends to designate a nonproprietary name that is a combination of the core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters.

In the *Federal Register* of August 28, 2015 (80 FR 52296), FDA announced the availability of a draft guidance, "Nonproprietary Naming of Biological Products," dated August 2015. In this notice, FDA solicited comments on several issues, including questions related to the application of the naming convention to previously licensed biological products (that is, biological products that are licensed without an FDA-designated suffix in their proper names); and the format of the suffix assigned to interchangeable products. The 2015 draft guidance specifically sought comment on whether the nonproprietary name for an interchangeable product should include a unique, distinguishing suffix, or should share the same suffix as its reference product.

FDA announced the availability of the final guidance dated January 2017 in the *Federal Register* of January 13, 2017 (82 FR 4345). The final guidance explained that the Agency was still considering the process to implement this naming convention for previously licensed biological products and for transition biological products, as well as the appropriate suffix format for interchangeable products.

FDA reviewed the comments received for both the draft and final versions of the guidance. FDA received comments indicating that revising the nonproprietary names of a large number of products licensed without an FDA-designated suffix in their proper names would create a substantial burden for healthcare systems, could cause disruption for product inventory, and could cause confusion for healthcare providers and patients, as the nonproprietary names of drugs seldom change postapproval. FDA considered these and other comments and, for reasons including those just described, does not intend to apply the naming convention to biological products licensed under the PHS Act without an FDA-designated suffix in their proper names.

For similar reasons, FDA does not intend to apply the naming convention to transition biological products.

FDA's current thinking is that the objectives of the naming convention described in the Naming Guidance can be accomplished without revising the nonproprietary names of: (1) biological products licensed under section 351 of the PHS Act without an FDA-designated suffix in their proper names or (2) transition biological products. In addition, only applying the naming convention prospectively is expected to reduce burden. Commenters have expressed concerns that modifications to patient recordkeeping systems, inventory systems, and other databases would be necessary to accommodate changes to the nonproprietary names of previously licensed products. Not applying the naming convention to biological products that were licensed without an FDA-designated suffix in their proper names nor to transition biological products avoids the potential burden on various stakeholders of changing the proper names of a large number of biological products.

Vaccines are currently within the scope of the naming convention described in the Naming Guidance. However, as stated in the draft guidance, FDA is reconsidering that approach and is evaluating whether the currently available identification systems associated with the administration of vaccines are sufficiently robust to ensure safe dispensing practices and optimal pharmacovigilance without requiring distinguishable proper names.

In addition, this draft guidance explains FDA's current thinking on the appropriate format of the suffix included in the nonproprietary name of interchangeable products. FDA's current thinking is that a suffix included in the nonproprietary name of an interchangeable product should, as with other biological products within the scope of the guidance, be a unique,

distinguishing suffix. FDA believes a unique, distinguishing suffix is necessary to achieve adequate pharmacovigilance for interchangeable products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). Based on the comments received in the docket, we intend to revise the final guidance for industry, "Nonproprietary Naming of Biological Products" dated January 2017, and to amend sections, such as sections IV.D and V.B, in that document regarding the subjects addressed in this draft guidance. This draft guidance is not intended to be finalized as a separate guidance document. When revised, the guidance will represent the current thinking of FDA on "Nonproprietary Naming of 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.

FDA invites comments on the draft guidance, as well as general comments on how the Agency may implement the naming convention described in the Naming Guidance in a manner that is fair and consistent while also promoting the specific objectives described in the Naming Guidance and avoiding unnecessary burden. For example, FDA invites comments regarding the implications of providing the same or a different suffix for the same drug substance that is submitted by the same sponsor for multiple strengths, dosage forms, or presentations in the same BLA, in a supplement to an approved BLA, or in a different BLA. FDA also invites comments on the application of the naming convention to vaccine products.

II. Paperwork Reduction Act of 1995

This draft guidance describes information collection provisions 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). In particular, the draft guidance refers to a new collection of information described in the final guidance, "Nonproprietary Naming of Biological Products," recommending that applicants propose a suffix composed of four lowercase letters to be included in the proper name. The proper name is designated by FDA at the time of licensure for biological products submitted under section 351(a) of the PHS Act and for biosimilar products and interchangeable products submitted under section 351(k) of the PHS Act. FDA is soliciting public comment, in a separate document published elsewhere in this issue of the *Federal Register* (see "Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Suffix for the Proper Name of a Biological Product") on the information collection associated with the guidance, "Nonproprietary Naming of Biological Products." FDA will also seek OMB approval for the information collection.

III. Electronic Access

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

Dated: March 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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