



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Nonproprietary Naming of Biological 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 guidance for industry entitled “Nonproprietary Naming of Biological Products.” The guidance describes our current thinking on the need for biological products previously and newly licensed under the Public Health Service Act (PHS Act) to bear nonproprietary names that include FDA-designated suffixes. Accordingly, we intend to designate nonproprietary names for originator biological products, related biological products, or biosimilar products which will include a core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. This guidance finalizes the draft guidance issued on August 28, 2015.

FDA is also announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit either electronic or written comments on Agency guidances at any time.

Submit written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory

Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-New and title “Nonproprietary Naming of Biological Products.” Also include the FDA docket number found in brackets in the heading of this document.

You may submit comments 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): 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-2013-D-1543 for “Nonproprietary Naming of 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 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 <https://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 docket, 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 <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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 (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 that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Regarding the guidance: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6340, 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.

Regarding the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “Nonproprietary Naming of Biological Products.” The guidance describes our current thinking on the need for biological products licensed under section 351(a) and (k) of the PHS Act (42 U.S.C. 262(a) and (k)) to bear a nonproprietary name that includes an FDA-designated suffix. Under this naming convention, the nonproprietary name designated for each originator biological product, related biological product, and biosimilar product will be a proper name that is a combination of the core name and a distinguishing suffix that is devoid of meaning and composed of four lowercase letters. The suffix format described in this guidance is applicable to originator biological products, related biological products, and biosimilar products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act. FDA is continuing to consider the appropriate suffix format for interchangeable biological products.

This naming convention will facilitate pharmacovigilance for originator biological products, related biological products, and biosimilar products containing related drug substances when other means to track a specific dispensed product are not readily accessible or available. Distinguishable nonproprietary names will also facilitate accurate identification of these biological products by health care practitioners and patients. Further, distinguishing suffixes should help minimize inadvertent substitution of any such products that have not been

determined to be interchangeable. Application of the naming convention to biological products licensed under the PHS Act should (1) encourage routine use of designated suffixes in ordering, prescribing, dispensing, recordkeeping, and pharmacovigilance practices and (2) avoid inaccurate perceptions of the safety and effectiveness of biological products based on their licensure pathway, as described in detail in the guidance.

The guidance provides information to industry, the health care community, other regulatory agencies, and the public on FDA's rationale for this naming convention. The guidance is also intended to assist applicants and application holders in proposing the suffix to be incorporated into an originator biological product, related biological product, or biosimilar product's nonproprietary name.

In the Federal Register of August 28, 2015 (80 FR 52296), FDA announced the availability of the draft guidance of the same title. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In the notice announcing the draft guidance, FDA asked about the benefits and challenges of designating (1) a suffix that is devoid of meaning versus meaningful (e.g., derived from the name of the license holder) and (2) a suffix that is unique to each biological product versus shared by each biological product manufactured by that license holder. FDA determined that the suffix format that best achieves the goals described in the guidance is a suffix that is devoid of meaning and not shared by each biological product manufactured by that license holder.

FDA intends to apply a naming convention to interchangeable products that will feature a core name and a suffix included in the proper name; however, FDA is continuing to consider the appropriate format of the suffix for these products.

This guidance also will apply to those biological products that are approved under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) on or before March 23, 2020, when such products are deemed to be licensed under section 351 of the PHS Act on March 23, 2020 (section 7002(e)(2) through (e)(4) of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act)). FDA intends to provide additional guidance regarding administrative issues associated with the transition (including the process for implementing the naming convention described in this guidance).

For the purposes of the guidance, unless otherwise specified, references to biological products include biological products licensed under the PHS Act, such as therapeutic protein products, vaccines, allergenic products, and blood derivatives, and do not include certain biological products that also meet the definition of a device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), such as in vitro reagents (e.g., antibody to hepatitis B surface antigen, blood grouping reagents, hepatitis C virus encoded antigen) and blood donor screening tests (e.g., HIV and hepatitis C). Also, for the purposes of the guidance, unless otherwise specified, references to biological products do not include products for which a proper name is provided in the regulations (e.g., 21 CFR part 640) or to certain categories of biological products for which there are well-established, robust identification and tracking systems to ensure safe dispensing practices and optimal pharmacovigilance (e.g., ISBT 128 for cord blood products and blood components).

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 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.

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## II. Paperwork Reduction Act of 1995

### Nonproprietary Naming of Biological Products

#### OMB Control Number 0910-New

The guidance describes FDA's current thinking on the need for biological products licensed under the PHS Act to bear a nonproprietary name that includes an FDA-designated suffix. There is a need to clearly identify biological products to facilitate pharmacovigilance and safe use. Accordingly, for originator biological products, related biological products, or biosimilar products licensed under the PHS Act, FDA intends to designate a nonproprietary name that includes a core name and a distinguishing suffix. This naming convention is applicable to biological products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act.

The final guidance proposes a new collection of information by requesting that applicants and application holders propose a suffix composed of four lowercase letters for use as the suffix included in the proper name. The proper name is designated by FDA in the license for biological products licensed under the PHS Act. The suffix will be incorporated in the nonproprietary name of the product. The guidance recommends that applicants and application holders submit up to 10 proposed suffixes, in the order of the applicant's preference. FDA also recommends including supporting analyses demonstrating that the proposed suffixes meet the factors described in the final guidance for FDA's consideration.

As indicated in table 1, we estimate that we will receive a total of approximately 40 requests annually for the proposed proper name for biological products submitted under section 351(a) of the PHS Act and six requests annually for the proposed proper name for biological products submitted under section 351(k) of the PHS Act. The average burden per response (hours) is based on the Agency's experience with similar information collection requirements for applicants to create and submit suffix proposals to FDA.

As noted, in the Federal Register of August 28, 2015, FDA published a 60-day notice requesting public comment on the proposed collection of information. Most comments supported FDA's proposal to designate a suffix. Many comments suggested that a meaningful, distinguishable suffix may help to improve pharmacovigilance, enhance safety, and facilitate identification between biological products. Some comments supported use of a random suffix to avoid creating an unfair advantage for specific manufacturers. Several comments stated that the current practices of FDA and non-FDA entities for identifying products is sufficient for the purpose of pharmacovigilance, and designation of a suffix is not needed. One comment stated that FDA's estimate of 6 hours to submit proposed suffixes is based only on the time needed to prepare the submission itself after the multiple suffixes have been selected. The comment further stated that because FDA suggests that each respondent submit three suggested suffixes for Agency consideration, the time needed to do an analysis of each suffix would exceed 720 hours per suffix (based on their own company experience) or 2,160 hours total for the three suffixes. The commenter subsequently submitted additional information to clarify how the estimates were calculated.

Response: FDA's estimate of the annual reporting burden results from information that would be submitted to FDA by applicants in order to facilitate FDA's designation of a suffix as

part of the proper name of a biological product. We estimated that sponsors would spend 2 hours completing the submission for each of the three suffixes, resulting in 6 hours as the average burden. This estimate for submission of the requested information is based on the average number of responses per respondent and the average burden per response over a 3-year period. FDA understands that there is a certain amount of research and other costs that an applicant might encounter in analyzing any proposed name for a biological product. FDA also recognizes that the burden may be higher for some applicants and lower for other applicants based on a variety of factors specific to the applicant.

The comment suggests that it will take 720 hours to complete an analysis and submission for each suffix. We have considered the information provided in support of this estimate and believe the estimate is likely too high. Our original estimate of 6 hours was based on the Agency's familiarity with the time it would take to make similar submissions to FDA. However, as identified by the comment, FDA's original estimate failed to adequately account for the time spent on creating proposed suffixes. We have reconsidered our original estimate as a result of the comment, and we have revised our estimate to account for the burden to create and submit up to 10 proposed suffixes to FDA for designation. As indicated in table 1, we estimate an average burden of approximately 420 hours to account for creating and submitting multiple proposed suffixes.

FDA estimates the information collection burden as follows:

Table 1.--Estimated Annual Reporting Burden <sup>1</sup>					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Information for the Proposed Proper Name for Applicable Biological Products Submitted Under Section 351(a) of the PHS Act	20	2	40	420	16,800
Information for the Proposed Proper Name for Applicable Biological Products Submitted Under Section 351(k) of the PHS Act	3	2	6	420	2,520
Total					19,320

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information related to the submission of a BLA under section 351(k) of the PHS Act (biosimilar products and interchangeable products) has been approved under OMB control number 0910-0719. The guidance also refers to a previously approved collection of information found in FDA regulations that is expected to change as a result of the guidance and the retrospective application of the naming convention. The collections of information in 21 CFR part 601 related to the submission of a biologics license application (BLA) and changes to an approved application have been approved under OMB control number 0910-0338. As a result of the guidance, the estimated number of additional responses for the annual burden for changes to an approved application under § 601.12 would be increased by approximately 25 responses.

FDA is issuing this final guidance subject to OMB approval of the collections of information. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the collections of information, including OMB control number(s) for newly approved collections.

### III. Electronic Access

Persons with access to the Internet may obtain the guidance at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: January 10, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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