Our estimated burden for the information collection reflects a decrease of 15 responses and a corresponding overall decrease of 120 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: March 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04207 Filed 3–7–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1543]

Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Suffix for the Proper Name of a Biological Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on Proposed Suffix for the Proper Name of a Biological Product.

DATES: Submit either electronic or written comments on the collection of information by May 7, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 7, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 7, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 ''Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Suffix for the Proper Name of a Biological Product.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Proposed Suffix for the Proper Name of a Biological Product

OMB Control Number 0910—New

The final guidance for industry, ''Nonproprietary Naming of Biological Products,'' proposes a new collection of information by 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 Public Health Service Act (PHS Act) (42 U.S.C. 262(a)) and for biosimilar products and interchangeable products submitted under section 351(k) of the PHS Act. The guidance recommends an applicant submit up to 10 proposed suffixes and include any analyses of how the proposed suffixes meet the factors described in the final guidance for industry. FDA's evaluation will generally occur during the investigational new drug application phase and will also be incorporated into the review of the marketing application.

FDA previously published a 60-day notice in the **Federal Register** of August 28, 2015 (80 FR 52296), and a 30-day notice in the **Federal Register** of January 13, 2017 (82 FR 4345), on this proposed collection of information. OMB did not reach a decision on this collection of information, withdrawing it on July 3, 2018. Consistent with the revisions proposed in the draft guidance, entitled ''Nonproprietary Naming of Biological Products—Update,'' FDA is re-initiating the notice and comment process for this collection of information, beginning with this 60-day notice.

Published elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled ''Nonproprietary Naming of Biological Products: Update.'' This draft guidance proposes to amend the final guidance, ''Nonproprietary Naming of Biological Products.'' The draft guidance describes, among other things, FDA's current thinking on nonproprietary (proper) names of biological products licensed under section 351 of the PHS Act that do not include an FDA-designated suffix. Specifically, the proper 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, '' dated January 2017. This draft guidance is not intended to be finalized. Based on the comments received on this draft guidance, FDA intends to revise the final guidance, ''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.

Consistent with the Draft Guidance, FDA proposes to gather the same type of information contemplated by the withdrawn information collection request (80 FR 52269 and 82 FR 4345). Due to the revisions proposed in the draft guidance, however, FDA anticipates that the number of respondents will be reduced, and FDA has re-estimated the burden of the collection of information accordingly. The proposed collection of information described in this notice is a new collection of information only and does not include a modification of an existing collection of information as previously recommended as part of the 60-day (80 FR 52296) and 30-day (82 FR 4345) notices of the **Federal Register**.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number 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	15	1	15	420	6,300
Information for the Proposed Proper Name for Applicable Biological Products Submitted Under Section 351(k) of the PHS Act	9	1	9	420	3,780
Total					10,080

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

As indicated in table 1 above, we estimate that we will receive a total of approximately 15 requests annually for the proposed ''proper name'' for biological products submitted under section 351(a) of the PHS Act and 9 requests annually for the proposed ''proper name'' for biosimilar products and interchangeable products submitted under section 351(k) of the PHS Act. The estimated total annual responses are based on data from user fee rates for fiscal year 2019. The number of responses per respondent has been updated to reflect FDA's most recent information on the number of applications that are expected to be submitted under 351 of the PHS Act to the Agency annually. The average burden per response (hours) is based on FDA's consideration of comments received in response to the 60-day and 30-day notices requesting public comment on the withdrawn information collection request associated with the final guidance (80 FR 52269 and 82 FR 4345).

Dated: March 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04241 Filed 3–7–19; 8:45 am]

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