4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Nonproprietary Naming of Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is 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: Fax 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 oira_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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

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

Guidance for Industry on Nonproprietary Naming of Biological Products

OMB Control Number 0910-NEW

The guidance entitled "Guidance for Industry on Nonproprietary Naming of Biological Products" describes FDA's current thinking on the need for biological products licensed under the Public Health Service Act (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, for the purposes of safe use, to minimize inadvertent substitution. Accordingly, for biological 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 (42 U.S.C. 262(a) or 262(k)).

The guidance includes information collection by requesting that applicants propose a suffix composed of four lowercase letters for use as the distinguishing identifier included in the proper name designated by FDA at the time of licensure 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 should submit up to 10 proposed suffixes, in the order of the applicant's preference. We also recommend including supporting analyses demonstrating that the proposed suffixes meet the factors described in the guidance for FDA's consideration.

As indicated in table 1, we estimate that we will receive a total of 40 requests annually for the proposed proper name for biological products submitted under section 351(a) of the PHS Act, and 6 requests annually for the proposed proper name for biosimilar products and interchangeable products submitted under section 351(k) of the PHS Act. The average burden per response (hours) is based on our experience with similar information collection requirements for applicants to create and submit suffix proposals to FDA and in consideration of comments received in response to our 60-day notice.

In the Federal Register of August 28, 2015 (80 FR 52296), we published a 60-day notice requesting public comment on the proposed collection of information. Most comments supported our 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 biosimilar and interchangeable 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 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.

In response to the comments we note that our estimated annual reporting burden results from information that would be submitted to us by applicants in order to facilitate Agency

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 is an annualized figure based on the average number of responses per respondent and the average burden per response over a 3-year period. We understand 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. We also recognize 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 suggesting that it will take 720 hours to complete an analysis and submission for each suffix does not provide a basis by which the estimate was calculated or whether it is broadly applicable. We find this figure rather high and retain our original estimate of 6 hours. The latter figure is based on our familiarity with the average amount of time required by similar submissions to FDA. At the same time, the comment also suggested that we failed to adequately account for the time spent on creating proposed suffixes. In consideration, therefore, we have revised our estimate upward to account for burden associated with creating and submitting up to 10 proposed suffixes for designation, as reflected in table 1.

FDA estimates the information collection burden as follows:

Description of Respondents: Respondents to the collection are sponsors of biological product applications.

Table 1.--Estimated Annual Reporting Burden[1]					
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 Biological Products Submitted Under Section 351(a) of the PHS Act	20	2	40	420	16,800
Information for the Proposed Proper Name for Biosimilar Products and Interchangeable Products Submitted Under Section 351(k) of the PHS Act	3	2	6	420	2,520
Total					19,320

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

The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information for the submission of a biologics license application (BLA) and changes (supplements) to an approved application under 21 CFR part 601 have been approved under OMB control number 0910-0338. The collections of information for the submission of a BLA under section 351(k) of the PHS Act (biosimilar products and interchangeable products) have been approved under OMB control number 0910-0719.

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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