TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]—Continued

21 CFR section	Form FDA number/ description	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.14	1997/Sanitary inspections of plants.	1	1	1	2.0	2
1210.20	1993/Application for permit	1	1	1	0.5 (30 minutes)	1
1210.23	1815/Permits granted on certificates.	1	1	1	0.5 (30 minutes)	1
Total	.....	.....	.....	.....	.....	306

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1210.15/Pasteurization records	1	1	1	0.05 (3 minutes)	1

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. In the past, Form FDA 1815 has been submitted in lieu of these forms. Because we have not received any Forms FDA 1994 or 1995 in the last 3 years, we assume no more than one will be submitted annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by OMB under the PRA. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Based on a review of the information collection since our last OMB approval, we have retained our burden estimate. The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. However, we have not received any responses in the last 3 years; therefore, we estimate that one or fewer to be submitted annually. Although we have not received any responses in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need for a milk importer.

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

[2] Numbers have been rounded.

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16101 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2581]

Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers; Draft 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 draft guidance for industry entitled ''Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers.'' This draft guidance provides answers to commonly asked questions from applicants and other interested parties regarding postapproval manufacturing changes made to biosimilar and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act).

DATES: Submit either electronic or written comments on the draft guidance by September 23, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on 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–2024–D–2581 for ''Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

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 to 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nidhi Pamidimukkala, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6652, Silver Spring, MD 20993–0002, 301–796–3397, *Nidhi.Pamidimukkala@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers.'' This draft guidance provides answers to commonly asked questions from applicants and other interested parties regarding postapproval manufacturing changes (referred to as manufacturing changes throughout this notice) made to biosimilar and interchangeable biosimilar products licensed under section 351(k) of the PHS Act (42 U.S.C. 262(k)). FDA is publishing this draft guidance to fulfill the commitment made in the 2022 reauthorization of the Biosimilar User Fee Act (BsUFA III, Title IV—Fees Relating to Biosimilar Biological Products, Pub. L. 112–144) for fiscal years 2023 through 2027. This draft guidance is intended to inform applicants on the nature and type of information, for different reporting categories, that applicants should provide to support manufacturing changes to licensed biosimilars and licensed interchangeable biosimilars.

In the **Federal Register** of September 20, 2021 (86 FR 52154), FDA published the notice of availability of a guidance for industry entitled ''Questions and Answers on Biosimilar Development and the BPCI Act,'' available at *https://www.fda.gov/media/119258/download* (Q&A biosimilar development guidance) to provide answers to commonly asked questions from applicants and other interested parties regarding the licensure of biosimilars under the Biologics Price Competition and Innovation Act of 2009. Postapproval manufacturing changes to biosimilars was the subject of Q&A I.20 in the Q&A biosimilar development guidance. FDA did not provide recommendations for interchangeable biosimilar products because FDA had limited knowledge and experience regarding manufacturing changes for licensed interchangeable biosimilar products when that guidance issued. FDA has since determined that the principles that apply to manufacturing changes for biosimilars are relevant to interchangeable biosimilar products. Thus, this draft guidance applies to manufacturing changes made to both licensed biosimilar and licensed interchangeable biosimilar products.

FDA may withdraw a Q&A that was previously in a guidance if FDA determines that the issue described in the Q&A is addressed in another guidance. Therefore, FDA intends to withdraw Q&A I.20 from the Q&A biosimilar development guidance when this draft guidance becomes final. FDA intends for this draft guidance to serve as a stand-alone guidance from the Q&A biosimilar development guidance and will not retain the same numbering of that guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of

information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 201.56 and 201.57 pertaining to prescription product labeling requirements have been approved under OMB control number 0910–0572; the collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139; the collections of information in section 351(k) of the PHS Act pertaining to biosimilar and interchangeable biosimilar product applications have been approved under OMB control number 0910–0718; and the collections of information in section 351 of the PHS Act and 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 16, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16128 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0795]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''Electronic Records: Electronic Signatures'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On December 21, 2023, the Agency submitted a proposed collection of information entitled ''Survey on Quantitative Claims in Direct-to-Consumer Prescription Drug Advertising'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0929. The approval expires on June 30, 2027. A copy of the supporting statement for this information collection is available on the internet at *https://www.reginfo.gov/public/do/PRAMain.*

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16096 Filed 7–22–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2931]

Agency Information Collection Activities; Proposed Collection; Comment Request; Microbiological Testing and Corrective Measures for Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which both domestic and foreign bottled water manufacturers that sell bottled water in the United States maintain records of microbiological testing and corrective measures, in addition to existing recordkeeping requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by September 23, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 23, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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.''