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

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Labeling applicable to medical gas containers; §§ 201.161(b) and 201.328	260	1,663	432,380	0.17 (10 minutes)	73,505
Exemption from barcode requirements § 201.25(d)	2	1	2	24	48
Safety labeling required under section 505(o)(4) of the FD&C Act, and re-buttal statement.	36	1	36	6	216
Safety labeling changes; posting approved letter on application holder's website.	351	1	351	4	1,404
Exceptions or alternatives to labeling requirements for human drug product held by SNS; § 201.26.	1	1	1	32	32
Hypertension claims; recommended labeling considerations	5	1	5	18	90
Total			433,324		1,913,896

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

Based on our evaluation, we have retained the currently approved estimate that 414 applicants will prepare an average of 549 prescription drug labels annually and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application.

New medical gas containers must meet applicable requirements found in 21 CFR part 211, as well as specific labeling requirements in § 201.328. Consistent with statutory authority under the Consolidated Appropriations Act, 2017 (Pub. L. 115–31), we have revised the information collection to include burden associated new medical gas labeling requirements under § 201.161(b), established by final rule in the **Federal Register** of June 18, 2024 (89 FR 51738). We estimate 260 respondents will incur burden for the design, testing, production, and submission of labeling for new medical gas containers as established in § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

Based on our evaluation, few requests for exemption from barcode requirements are received, and we have therefore made no changes to the currently approved estimate for this activity. Likewise, we have also retained the currently approved estimate for information collection activities associated with safety labeling requirements established in section 505(o)(4) of the FD&C Act. Similarly, we retain the currently approved estimate for exceptions to labeling under § 201.26; however, this activity was previously approved in OMB control number 0910–0614 and is a new element to the collection, adding 1 response and 32 hours annually.

Finally, we have combined activity elements associated with labeling recommendations regarding drugs products that include a hypertension indication as discussed in the applicable March 2011 guidance referenced above, reducing the overall estimate for this element by 4 hours annually.

Dated: January 28, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–02154 Filed 1–30–25; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–D–3067; FDA–2024–D–3863]

Guidance for Industry; Recommendations To Reduce the Risk of Transmission of Disease Agents Associated With Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products; Recommendations To Reduce the Risk of Transmission of Mycobacterium Tuberculosis by Human Cells, Tissues, and Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The final guidances entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' and ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' are being revised to change the time by which FDA recommends implementation of the recommendations in the guidances.

DATES: The announcement of these guidances is published in the **Federal Register** on February 3, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–3067 for ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' or the Docket No. FDA–2024–D–3863 for ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' as appropriate. 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 guidances to the 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 labels to assist that office in processing your requests. The guidances 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 guidance documents.

FOR FURTHER INFORMATION CONTACT: James Myers, 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 two revised final guidances, ''Recommendations to Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' and ''Recommendations to Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' These guidance documents were originally published in the **Federal Register** on January 7, 2025 (90 FR 1141; 90 FR 1170). Both guidances recommended that establishments making donor eligibility determinations (establishments) implement the recommendations in the guidances ''as soon as feasible, but not later than 4 weeks after the guidance issue date.''

FDA is revising final guidances ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' and ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' to recommend implementation of the guidance recommendations on a longer timeframe, by May 4, 2025. The revised implementation date will permit FDA to consider the comments received thus far prior to the implementation date. Permitting the Agency additional time to further review and consider the guidances, including comments received, as well as seek additional comments is consistent with the President's January 20, 2025, memorandum entitled, ''Regulatory Freeze Pending Review.'' See paragraph 3 (directing agencies to consider postponing effective dates of certain rules ''for the purpose of reviewing any questions of fact, law, and policy that the rules may raise''; ''where appropriate and consistent with applicable law, consider opening a comment period to allow interested parties to provide comments about issues of fact, law, and policy raised by the rules postponed under this memorandum''; and consider further delaying such rules ''where necessary to continue to review these questions of fact, law, and policy'').

FDA issued the guidance entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of disease agents associated with sepsis for donors of human cells, tissues, and cellular and tissue-based products.

FDA issued the guidance entitled ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' to assist establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products, with recommendations for screening donors for evidence of, and risk factors for, infection with Mtb, the organism that causes tuberculosis.

FDA is issuing these revised guidances consistent with our good guidance practices regulation (§ 10.115 (21 CFR 10.115)). We are implementing these revisions without prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)). We made this determination because the revisions present a less burdensome policy that is consistent with public health. Although these guidance documents are being implemented immediately, you can comment on any guidance at any time (§ 10.115(g)(5)). FDA has already received comments on the guidances discussed above, and the Agency

intends to consider those comments. Please submit any additional comments regarding the guidances that you wish the Agency to consider, including whether it would be appropriate to reissue these guidances in draft form or consider a later implementation date.

II. Paperwork Reduction Act of 1995

While these guidance documents contain no collection of information, they do 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 1271 relating to HCT/Ps, including establishing and maintaining records, investigation and reporting of adverse actions and documentation of methods used in facilities related to HCT/Ps, which, includes but is not limited to donor screening, donor testing, and labeling have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidances at *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.*

Dorothy A. Fink,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2025–02167 Filed 1–31–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4146]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by March 5, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0718. Also include the FDA docket number found in brackets in the heading of this document.

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

Biosimilars User Fee Program

OMB Control Number 0910–0718—Revision

This information collection supports FDA's Biosimilars User Fee Program and implementation of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The BPCI Act creates an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379g) to include 351(k) applications as a type of application under ''human drug application'' for the purposes of the prescription drug user fee provisions. The FD&C Act as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), reauthorizes FDA to assess and collect fees for biosimilar biological products from October 2022 through September 2027 to facilitate the development of safe and effective biosimilar products for the American public.

FDA maintains information on our website at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments* regarding its BsUFA program. Also available on our website is the Biosimilars Action Plan (BAP), which discusses key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars. The BAP builds on progress in implementing the approval pathway for biosimilar and interchangeable products, and provides interested persons with updates on related deliverables and activities.

We have revised the information collection to reflect the currently agreed-upon performance goals established and captured in the latest reauthorization document entitled, ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' (BsUFA Commitment Letter). The BsUFA Commitment Letter is available for download from our website at *https://www.fda.gov/media/152279/download?attachment.* The BsUFA Commitment Letter outlines current program goals, including information technology goals, discusses program effectiveness considerations, and discusses user fee resource management.

The information collection also includes Form FDA 3792, ''Biosimilars User Fee Cover Sheet,'' to be submitted by each new biological product development (BPD) entrant (identified via a new meeting request or investigational new drug submission) or new biologics license application (BLA) applicant. Form FDA 3792 requests the minimum information necessary to identify the request, to determine the amount of the fee to be assessed, and to account for and track user fees. Form FDA 3792 is completed electronically at *https://userfees.fda.gov/OA_HTML/bsufaCAcdLogin.jsp,* and a notification is emailed to the respondent that includes information regarding annual program fees. We are discontinuing use of the associated annual survey at this time.

Relatedly, Form FDA 3971 (Small Business Waiver and Refund Request), currently approved in OMB control number 0910–0297, may also be utilized. As instructed on our BsUFA web page, respondents should submit Form FDA 3971 by email to *CDERCollections@fda.hhs.gov* at least 4 months prior to the submission of the application to see if they qualify for a small business waiver. Finally, user fee refund and transfer requests, currently approved in OMB control number 0910–