DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4167]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling Requirements for Prescription Drugs

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

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 0910–0572. 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.

Labeling Requirements for Prescription Drugs

OMB Control Number 0910–0572—Revision

This information collection helps implement statutory and regulatory requirements that govern the labeling of prescription drugs. FDA regulations codified in part 201 (21 CFR part 201), subpart B (§§ 201.50 through 201.58), apply to requisite labeling elements that include a statement of identity; a declaration of net quantity of contents; a statement of dosage; and specific content and formatting of information. The regulations also provide for requesting that FDA waive any requirement under §§ 201.56, 201.57, and 201.80. Since last approval of the information collection, FDA requested, and OMB approved, adding tasks provided for under § 201.25(d), requiring that manufacturers submit a written request for exemption from applicable barcode requirements, and tasks relating to exceptions or alternatives to the labeling requirements of products in the Strategic National Stockpile (SNS) as provided for in § 201.26, to the scope of the activity. Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the security of the Nation (section 319F–2 of the PHS Act (42 U.S.C. 247d–6b). Information regarding the SNS is available at the following website: *www.phe.gov/about/sns/Pages/default.aspx.*

Relevant information regarding applicable statutory and regulatory requirements are also discussed in topic-specific guidance documents issued consistent with 21 CFR 314.445, 21 CFR 601.29 (guidance documents), and Agency Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. The following guidance documents discuss activities included in the information collection:

''Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act'' (FD&C Act) (78 FR 45930, July 30, 2013). The guidance document includes instruction on communicating with FDA regarding labeling changes required under section 505(o)(4) (Section IV—Procedures) (21 U.S.C. 355(o)(4)) and is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-labeling-changes-implementation-section-505o4-federal-food-drug-and-cosmetic-act.*

''Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims'' (76 FR 14024, March 15, 2011). The guidance document is intended to help respondents with developing labeling for cardiovascular outcome claims for drugs that are indicated to treat hypertension. The guidance document is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hypertension-indication-drug-labeling-cardiovascular-outcome-claims.*

Respondents to the information collection are sponsors of product labeling subject to the applicable labeling requirements. We characterize the information collection activities as recordkeeping, consistent with 5 CFR 1320.3(m), noting that a recordkeeping requirement means a requirement to maintain specified records, including the requirement to retain and notify third parties, the Federal Government, or the public regarding such records. Regulations in part 201 govern the statement of ingredients and declaration of net quantity of contents regarding prescription drug product labeling. The regulations require that firms identify bulk or transport containers with the name of the product contained therein and that containers be accompanied by documentation that identifies the product as meeting applicable compendial standards. New drug product and biological product applicants must: (1) design and create prescription drug labeling containing ''Highlights,'' ''Contents,'' and ''Full Prescribing Information''; (2) test the designed labeling (for example, to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval.

In the **Federal Register** of September 19, 2024 (89 FR 76853), we published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited.

We estimate the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Labeling requirements for prescription drugs; §§ 201.56 and 201.57	414	1.326	549	3,349	1,838,601

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 rebuttal 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.

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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.''