438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, 42 U.S.C. 299b-21 to 299b-26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

AHRQ has accepted a notification of proposed voluntary relinquishment from the Emergency Medical Error Reduction Group PSO to voluntarily relinquish its status as a PSO. Accordingly, the Emergency Medical Error Reduction Group PSO, P0235, was delisted effective at 12:00 Midnight ET (2400) on March 29, 2023.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

Dated: April 13, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–08247 Filed 4–18–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1338]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of April 11, 2023. The document announced a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation and International Affairs, Food and Drug Administration, 301–796–9115, *Lisa.Granger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, April 11, 2023 (88 FR 21688) in FR Doc. 2023–248, the following corrections are made:

1. On page 21688, in the third column, in the header of the document, ''Docket No. FDA–2023–N–0378'' is corrected to read ''Docket No. FDA–2023–N–1338'' and in the **ADDRESSES** section, in the third line of the last paragraph, ''FDA–2023–N–0378'' is corrected to read ''FDA–2023–N–1338.''

2. On page 21689, in the first column, in the second line of the ''Instructions:'' section, Docket No. FDA–2023–N–0378'' is corrected to read ''Docket No. FDA–2023–N–1338''.

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08279 Filed 4–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3065]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

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: Submit written comments (including recommendations) on the collection of information by May 19, 2023.

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 0910–0877. Also include the FDA docket number found in brackets in the heading of this document.

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

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements—21 CFR Part 1141

OMB Control Number 0910–0877—Extension

This information collection supports FDA regulations and guidance. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t).

On March 18, 2020, FDA issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' (85 FR 15638; *https://www.federalregister.gov/d/2020-05223*). The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 (FCLAA) (15 U.S.C. 1333) to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics.

Section 1141.10(g) (21 CFR 1141.10(g) and section 4(c) of the FCLAA sets forth the specific marketing requirements relating to the random and equal display and distribution of required warnings on cigarette packaging and quarterly rotation of required warnings in alternating sequence in cigarette advertising and requires the submission of plans outlining how the cigarette packaging and advertising will comply with such requirements. FDA must review and approve cigarette plans in advance of any person displaying or distributing cigarette packages or advertisements for products that are required to carry the required warnings, and a record of the FDA-approved plan must be established and maintained by the tobacco product manufacturer.

To implement these statutory and regulatory requirements, cigarette plans will be reviewed by FDA upon submission by respondents. FDA published a guidance document on July 9, 2021, entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements'' which describes cigarette plans information, format and submission (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-plans-cigarette-packages-and-cigarette-advertisements-revised*).

Pursuant to section 201(b) of the Tobacco Control Act, FDA finalized the ''Required Warnings for Cigarette Packages and Advertisements'' rule with an effective date of June 18, 2021, 15 months after the date of publication. On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] The effective date of the final rule has been delayed in accordance with orders issued by the U.S. District Court for the Eastern District of Texas. Visit FDA's website at *https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements* for updates regarding the effective date of the rule and related timelines, including the recommended date for submitting cigarette plans for FDA review.

In the **Federal Register** of September 19, 2022 (87 FR 57206), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Part 1141 and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Original Submission (Initial Plan)	59	1	59	150	8,850
Supplement	30	1	30	75	2,250
Total					11,100

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

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* smokeless, OMB control number 0910–0671 and cigars, OMB control number 0910–0768) and 2017 Treasury Alcohol and Tobacco Tax and Trade Bureau data.

FDA estimates 59 entities are affected. We estimate these 59 entities will submit initial plans, and it will take an average of 150 hours per respondent to prepare and submit a plan for packaging and advertising for a total of 8,850 hours. We estimate that about half of respondents will submit a supplement. If a supplement to an approved plan is submitted, FDA estimates it will take half the time per response. We estimate receiving 30 supplements at 75 hours per response for a total of 2,250 hours. FDA estimates that the total hours for submitting initial plans and supplements will be 11,100.

Section 1141.10(g)(4) establishes that each tobacco product manufacturer required to randomly and equally display and distribute warnings on cigarette packages or quarterly rotate warnings in cigarette advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and part 1141 must maintain a copy of the FDA-approved plan (approved under § 1141.10(g)(3)). This copy of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This subsection requires that the FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Part 1141 and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Original Submission (Initial Plan) Records	59	1.5	89	3	267
Total					267

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

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 3 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* smokeless, OMB control number 0910–0671 and cigars, OMB control number 0910–0768). Based on our estimates for the submission of one-time, initial plans and supplements (*i.e.,* that all respondents will submit one-time, initial plans and about half of respondents will submit supplements to FDA-approved plans), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA concludes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501–3521). Rather, these labeling statements are a ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of ''disclosure to the public'' (5 CFR 1320.3(c)(2)).

Since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08280 Filed 4–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1168]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products

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, 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 information collection associated with statutory and regulatory requirements that govern certain human cells, tissues, and cellular and tissue-based products (HCT/Ps).

DATES: Either electronic or written comments on the collection of information must be submitted by June 20, 2023.

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 June 20, 2023. 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.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–1168 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products.'' 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, 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