DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2002–N–0314; FDA–2018–N–0405; FDA–2018–N–0270; and FDA–2021–N–0359]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Request for Samples and Protocols	0910–0206	9/30/2024
Medical Device Recall Authority	0910–0432	9/30/2024
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types	0910–0799	9/30/2024
Human Drug Compounding, Repackaging and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–0858	9/30/2024

Dated: December 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–28299 Filed 12–28–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1529]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, 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 January 28, 2022.

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 0910–0138. 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.

Reclassification Petitions for Medical Devices

OMB Control Number 0910–0138—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) establishes the following three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I (general controls), class II (special controls), and class III (premarket approval) (section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). To change a device classification, FDA can initiate a reclassification, or an interested person can petition FDA to reclassify a device based on new information (section 513(e) of the FD&C Act). On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted, changing the reclassification process under section 513(e) of the FD&C Act from rulemaking to an administrative order process. To reclassify a device under section 513(e) of the FD&C Act, FDA must do the following before making the reclassification final: (1) Publish a proposed order in the **Federal Register** that includes the proposed reclassification and a summary of the valid scientific evidence that supports the reclassification, (2) convene a device classification panel meeting, and (3) consider comments from the relevant public docket.

FDASIA also amended the provisions of the FD&C Act authorizing FDA to require submission of a premarket approval application (PMA) for a preamendments class III device (referred to as a ''call for PMAs''). Preamendments devices are devices that were in commercial distribution before the enactment of the 1976 Amendments. Under the FD&C Act, preamendments devices classified into class III may be marketed upon clearance of a 510(k) submission, and submission of a PMA is not required until FDA has issued a final order requiring premarket approval (section 515(b) of the FD&C Act (21 U.S.C. 360e(b)). As amended by FDASIA, the FD&C Act requires that FDA, in its call for PMAs, publish a proposed order in the **Federal Register**, hold a classification panel meeting, and

consider comments on the proposed order (section 515(b) of the FD&C Act, as amended by FDASIA).

Under the FD&C Act, FDA's call for PMAs must, among other things, contain an opportunity for interested persons to request a change in the classification of the device based on new information (section 515(b)(2) of the FD&C Act). After consideration of comments on the proposed order and findings, FDA must either: (1) Finalize the call for PMAs by issuing an administrative order requiring approval of a PMA and publishing in the **Federal Register** findings with respect to: (i) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed product development protocol and (ii) the benefit to the public from the use of the device; or (2) publish a notice in the **Federal Register** terminating the proceeding and initiate a reclassification proceeding based on new information (section 515(b)(3) of the FD&C Act, as amended by FDASIA; see section 513(e) of the FD&C Act).

The FD&C Act, as amended by FDASIA, now requires the use of administrative orders, rather than rulemaking, when FDA calls for PMAs for a preamendments device remaining in class III (section 515(b) of the FD&C Act, as amended by FDASIA).

FDA refers to a device that was not in commercial distribution before the 1976 Amendments as a postamendments device. Postamendments devices are classified automatically into class III by statute, without any rulemaking process (section 513(f)(1) of the FD&C Act). A postamendments device remains in class III and is subject to the PMA requirements unless and until: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II via the De Novo classification process (see section 513(f)(2) of the FD&C Act); or (3) FDA issues an order finding the device to be substantially equivalent to a predicate device that does not require the filing of a PMA (see section 513(i) of the FD&C Act).

FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a postamendments device classified into class III by operation of law (section 513(f)(3) of the FD&C Act). This FDA-initiated reclassification process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments (§ 860.134(c) (21 CFR 860.134(c))). The reclassification order may, as appropriate, establish special controls to provide reasonable assurance of the safety and effectiveness of the device (§ 860.134(d)).

Under the 1976 Amendments, Congress classified all those devices previously regulated as new drugs into class III (generally referred to as transitional devices). Under the FD&C Act, FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a transitional device remaining in class III (section 520(l)(2) of the FD&C Act (21 U.S.C. 360j(l)(2)). The process for reclassification of transitional devices initiated by FDA is detailed in 21 CFR ?860.136(c). This process consists of a proposed reclassification order, optional panel consultation, and a final reclassification order published in the **Federal Register** following consideration of comments and any panel recommendations or comments.

In the **Federal Register** of September 7, 2021 (86 FR 50132), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 860.123; supporting data for reclassification petitions	6	1	6	497	2,982

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–0066—Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request SHIP COVID–19 Testing and Mitigation Program Data Collection

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 28, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.