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.

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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