Based on data currently available to FDA on the number of firms disseminating promotional communications about prescription drugs (697) combined with an estimated number of device firms marketing products (261), we assume that approximately 958 firms (''number of respondents'' in table 1) might each choose to disseminate 50 tailored responsive communications annually. Our estimate of the burden per disclosure reflects what we believe is the average burden based on the number and content and complexity of disclosures as recommended in the guidance.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314 are approved under OMB control number 0910–0001. The collections of information in 21 CFR part 201 regarding content and format of labeling for human drug and biological products are approved under OMB control number 0910–0572. The collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485. The collections of information in 21 CFR 202.1 regarding prescription drug advertising are approved under OMB control number 0910–0686. The collections of information in 21 CFR part 601 regarding marketing approval of biological products are approved under OMB control number 0910–0338; and the collections of information regarding marketing approval of animal drug products in 21 CFR part 514 are approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: July 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15009 Filed 7–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2844]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

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 information collection associated with reclassification of medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by September 9, 2024.

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 September 9, 2024. 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–2024–N–2844 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices.'' 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 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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reclassification Petitions for Medical Devices—21 CFR Part 860, Subpart C

OMB Control Number 0910–0138—Extension

This information collection helps support implementation of statutory provisions found in sections 513(e) and (f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(e) and (f), 21 U.S.C. 360d(b), 21 U.S.C. 360e((b), and 21 U.S.C. 360j(l)) pertaining to the reclassification of medical devices. Specifically, the FD&C Act establishes three tiers of regulatory control for medical devices, by establishing three classes of medical devices, and requiring that all devices be classified into one of these three classes. The classification of a device depends upon the degree of regulatory control necessary to provide a reasonable assurance of the safety and effectiveness of the device. The three tiers of regulatory control are: (1) Class I—general controls, subject to sections 501 adulteration, 502 misbranding, 510 registration, 516 banned devices, 518 notification and other remedies, 519 records and reports, and 520 general provisions of the FD&C Act; (2) Class II—performance standards; and (3) Class III—premarket approval.

Implementing regulations in 21 CFR part 860, subpart C (parts 860.120 through 860.136) provide that any person may petition for reclassification of a device from any class to any other class, and prescribe requisite format and content elements for reclassification petitions submitted to the Agency. We also provide information on our website at *https://www.fda.gov/about-fda/cdrh-transparency/reclassification* regarding medical device reclassification, which may serve as a helpful resource to respondents.

FDA is responsible for reviewing petitions for reclassification and determining whether the subject device will be reclassified. In some instances, FDA also submits such petitions to one of its medical device advisory panels for review and recommendations. FDA's decision regarding the reclassification of a device is based primarily upon the information contained in the petition. Respondents to the information collection are private sector, for-profit businesses. We have not identified reclassification petitions as a type of submission we are currently prepared to accept electronically. Submission instructions, including addresses, are provided in § 860.123(b).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part; 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	12	1	12	497	5,964

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

Reclassification petitions must be submitted as set forth in the applicable regulations, which provide for the submission of an original and two copies (§ 860.123(b)(4)). Each petition must include supporting data to show why reclassification of the device type will provide reasonable assurance of the safety and effectiveness of the device type. The principal data in such a petition will typically be reports of clinical trials.

Our estimated burden for the information collection reflects an increase of 6 responses and a corresponding increase of 2,982 hours. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: July 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14995 Filed 7–8–24; 8:45 am]

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