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).

In the **Federal Register** of July 9, 2024 (89 FR 56390), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, but it was not related to this information collection.

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: December 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29955 Filed 12–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4974]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Advanced Manufacturing Technologies Designation Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by January 17, 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 0910–0139. 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.

Advanced Manufacturing Technologies Designation Program

OMB Control Number 0910–0139—Revision

This information collection supports the establishment of an FDA Advanced Manufacturing Technologies (AMT) Designation Program, as provided for in section 506L of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356l). Intending to enhance the development of and combat the shortage of critical medical products, the AMT Designation Program encourages early adoption of new technological advances in manufacturing processes by the pharmaceutical industry or other drug/

biologic developers. FDA regulations in 21 CFR parts 210 and 211 govern current good manufacturing practice in the manufacturing, processing, packing, or holding of drugs and finished pharmaceuticals (including medical gases and active pharmaceutical ingredients), respectively. Applicable information collection and attendant burden are currently discussed, accounted for, and approved in OMB control number 0910–0139.

We are revising the information collection to include the AMT Designation Program within the scope of activity, as authorized by section 506L of the FD&C Act, and account for attendant burden. Requests for AMT designation are reviewed by FDA to evaluate whether the data and information submitted meets the criteria established in section 506L of the FD&C Act. If a request for AMT designation is granted, then future new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA) applicants may use or reference the designated AMT, noting specific application of the designated AMT to specific product development and inclusion in NDA, ANDA, or BLA submissions describing development and manufacturing processes. Also required by section 506L of the FD&C Act, we engaged with our stakeholders in a public meeting on June 8, 2023 (April 24, 2023, 88 FR 24807), to discuss innovative manufacturing technologies for drug and biological products and included a discussion of the AMT Designation Program. For more information regarding AMT, we invite readers to visit our website at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing,* which includes regular updates on Agency implementation of its AMT Designation Program.

Finally, section 506L of the FD&C Act also provides for the issuance of guidance. In the **Federal Register** of December 13, 2023 (88 FR 86333), we issued the draft guidance document entitled ''Advanced Manufacturing Technologies Designation Program,'' to communicate the goals, scope, and framework of the new program. We invited public comment under both our good guidance practices regulation in 21 CFR 10.115, and applicable PRA regulations in 5 CFR part 1320 and received a few comments. The comments included some requests for procedural clarification but focused mostly on requests for clarification of technical specifications and technologies that might qualify for AMT designation. Although we have updated the guidance document to address a number of public comments, we continue to implement the program and refine Agency processes.

FDA estimates the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 506L(c) FD&C Act	Number of respondents	Number of responses per respondents	Total annual responses	Average burden per response	Total hours
Submitting AMT designation requests; FDA Guidance for Industry, section III.B	20	1	20	10	200

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

Based on our experience with similar information collection activities that involve requests for FDA determinations, along with related preliminary and followup communications, we assume 10 hours is needed to complete the activities provided for in section 506L of the FD&C Act and discussed in the referenced guidance document. Although we have received fewer than 10 requests for AMT designation thus far, we are hopeful that 20 respondents will submit requests for AMT designation under the program.

Dated: December 11, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–29954 Filed 12–17–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–0195; FDA–2024–E–0196; FDA–2024–E–0197; FDA–2024–E–0198]

Determination of Regulatory Review Period for Purposes of Patent Extension; SOHONOS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SOHONOS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by February 18, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 16, 2025. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 February 18, 2025. 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,