

from marketing for reasons other than safety or effectiveness. ANDAs that refer to this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16863 Filed 9-2-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0953]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices; Foreign Letters of Approval

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 October 3, 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 0910-0264. 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, PRASStaff@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.

Export of Medical Devices; Foreign Letters Of Approval

OMB Control Number 0910-0264—Extension

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for

export. Requesters must communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States stating that the product is not in conflict with the foreign country’s laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to make a false or fraudulent statement knowingly and willingly, or make or use a false document, in any manner within the jurisdiction of a department or agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA’s estimate of the reporting burden is based on the experience of FDA’s medical device program personnel.

In the **Federal Register** of June 16, 2025 (90 FR 25339), 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 BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval— 801(e)(2)	36	1	36	2	72	\$10,080

¹ There are no capital 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-16850 Filed 9-2-25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-P-0100]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

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 October 3, 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 0910–0823. 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, 10 a.m.–12 p.m., 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.

Medical Device Accessories

OMB Control Number 0910–0823—Extension

FDA’s guidance document entitled “Medical Device Accessories—Describing Accessories and Classification Pathways” (December 2017) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-accessories-describing-accessories-and-classification-pathways>) is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA’s policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA generally considers an “accessory” and

describes the processes under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(6)) (FD&C Act) to allow requests for risk-and regulatory control-based classification of accessories.

The FDA Reauthorization Act of 2017 (FDARA) changed how FDA regulates medical device accessories. Specifically, section 707 of FDARA added section 513(f)(6) of the FD&C Act to the statute and requires that FDA, upon request, classify existing and new accessories notwithstanding the classification of any other device with which such accessory is intended to be used. This means that the classification of an accessory may not be the same as its parent device, depending on the risks of the accessory when used as intended and the level of regulatory controls necessary for reasonable assurance of safety and effectiveness of the accessory. Until an accessory is distinctly classified, its existing classification will continue to apply. This provision does not preclude a manufacturer from submitting a De Novo request for an accessory under section 513(f)(2) of the FD&C Act.

Depending on an accessory’s regulatory history, there are different submission types, tracking mechanisms, and deadlines:

(1) Existing accessory types are those that have been identified in a classification regulation or granted marketing authorization as part of a 510(k) (section 510(k) of the FD&C Act (21 U.S.C. 360(k)), premarket application (PMA) (section 515 of the FD&C Act (21 U.S.C. 360e)), or De Novo (section 513(f)(2) of the FD&C Act) request (approved under OMB control numbers 0910–0120, 0910–0231, and 0910–0844, respectively). Manufacturers with marketing authorization for an existing accessory may request appropriate classification through a new stand-alone premarket submission (Existing

Accessory Request). Upon request, FDA is required to meet with a manufacturer or importer to discuss the appropriate classification of an existing accessory prior to submitting a written request. Existing Accessory Requests will be initially tracked as “Q-submissions” (approved under OMB control number 0910–0756). FDA has a statutory deadline of 85 calendar days to respond to an Existing Accessory Request.

(2) New accessory types are those that have not been granted marketing authorization as part of a 510(k), PMA, or De Novo request. Manufacturers may include new accessories in a 510(k) or PMA with the parent device (New Accessory Request). New Accessory Requests will have the same deadline as the 510(k) or PMA. Therefore, new accessory types should follow the applicable Medical Device User Fee Amendments of 2017 deadline for the parent submission. The decision for New Accessory Requests will be separate from the decision for the marketing application.

For both Existing and New Accessory Requests, manufacturers must request proper classification of their accessory in the submission and include draft special controls, if requesting classification into class II. The processes that we use to classify an accessory will be like those used for De Novo requests. If FDA grants the Accessory Request, FDA must issue an order establishing a new classification regulation for the accessory type. If FDA denies the Accessory Request, FDA must issue a letter with a detailed description and justification for our determination.

In the **Federal Register** of June 16, 2025 (90 FR 25326), 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 BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Existing Accessory Request	10	1	10	40	400
New Accessory Request	5	1	5	40	200
Total	600

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-3215]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; FDA Food Safety and Nutrition Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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.

DATES: Submit written comments (including recommendations) on the collection of information by October 3, 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 0910-0345. 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.

Food Safety and Nutrition Survey

OMB Control Number 0910-0345—Reinstatement

Under section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), we are authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. In the past, FDA has conducted two separate surveys, a Food Safety Survey and a Health and Diet Survey, to measure consumers' knowledge, attitudes, and beliefs about food safety and nutrition issues. These surveys have been conducted every 3 to 5 years since the 1980s. In the **Federal Register** of August 14, 2018 (83 FR 40293), we announced the combination of these two surveys, which will now be the FDA Food Safety and Nutrition Survey (FSANS). Data from FDA's food safety and nutrition surveys have been used to support rulemaking and educational campaigns and to measure progress toward Healthy People 2010, 2020, and 2030 food safety goals. The proposed 2025 FSANS will contain many of the same questions and

topics as the previous surveys to facilitate measuring trends in food safety and diet knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety and nutrition topics and to expand understanding of previously asked topics.

The 2025 FSANS will be both a paper-and-pencil and web-based survey. Respondents will be contacted by postal mail, using an address-based sampling frame. Once contacted, respondents will be encouraged to take the survey online. A paper-and-pencil version of the survey will be mailed to those who do not initially take the web-based version of the survey. One randomly selected adult from each sampled household will be invited to participate in the survey using the Hagen-Collier method.¹ A total of 5,000 respondents will be surveyed. We will sample approximately 25,000 households to offset nonresponding households and ineligible addresses and achieve 5,000 adult respondents. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

Description of Respondents:

Respondents to this collection of information are individuals who are adults aged years 18 or older drawn from the 50 states and the District of Columbia.

In the **Federal Register** of July 31, 2024 (89 FR 61457), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it did not respond to any of the information collection topics solicited under the PRA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	18	1	18	1	18
Pretest	100	1	100	0.33 (20 minutes)	33
Mail survey	5,000	1	5,000	0.33 (20 minutes)	1,650
Total			5,193		1,707

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

FDA's burden estimate is based on the Agency's prior experience with food safety and nutrition surveys. We will use a cognitive interview screener with

75 individuals to recruit prospective interview participants for a total of 18 individuals. We estimate that it will take each screener respondent

approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 6 hours. We will conduct cognitive interviews with 18

¹ In this method, we randomly select a category based on sex and age (based on the sex-age

composition of the household), and then take the adult in that selected category.