4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0348]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Center for Devices and Radiological Health Appeals Processes

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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 0910-0738. 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.

Center for Devices and Radiological Health Appeals Processes

OMB Control Number 0910-0738 -- Revision

This information collection supports implementation of recommendations found in FDA guidance. As discussed in the document entitled "Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes" (March 2022), there are various processes by which appeals requests regarding review of decisions or actions by CDRH may be submitted to the Agency. The guidance is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes.* The guidance document provides general format and content recommendations in this regard, discusses applicable regulations with regard to the timing of such submissions, and describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information. While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of information as recommended in the guidance regarding the appeal request itself, as well as data and information relied on by the requestor in the appeal, will help facilitate timely resolution of the decision under review. We are accounting for burden respondents may incur as a result of these Agency recommendations in this collection request. Additional information about the CDRH appeals process is described in the companion guidance entitled "Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff" (March 2020), also available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a.*

In the *Federal Register* of July 3, 2025 (90 FR 29563), 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	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDRH Appeals Processes	75	1	75	8	600

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

Our estimated burden for the information collection reflects an overall increase of 320 hours and a corresponding increase of 40 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years. A review of prior renewals revealed that additional information about the CDRH appeals process is described in the companion guidance entitled "*Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff*" (March 2020) was omitted in the last approval cycle. This current revision adds this missing guidance to provide clarity and ensure completeness. No other changes affect the scope or burden of this information collection

Brian Fahey,

Associate Commissioner for Legislation.

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