Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

On March 20, 1998, FDA issued the guidance document, ''The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,'' which established the Special 510(k) Program. By establishing the Special 510(k) Program, FDA sought to create an efficient review process for certain changes subject to 510(k) submission requirements by leveraging design control requirements. The Special 510(k) Program allows manufacturers that are intending to change their own legally marketed device to utilize risk analysis and verification and validation activities to facilitate submission, review, and clearance of the change. While FDA intends to review Special 510(k)s within 30 days, the Special 510(k) Program does not alter any statutory or regulatory requirements related to the 510(k) process under sections 510 and 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360 and 360c) and 21 CFR part 807, subpart E.

To improve the efficiency of 510(k) review, FDA has updated the Special 510(k) Program to both clarify existing policy and the types of changes appropriate for the program. This guidance explains the factors FDA uses when considering whether a 510(k) is appropriate for review as a Special 510(k). In general, a change to an existing device may be appropriate for a Special 510(k) when: (1) The proposed change is submitted by the manufacturer legally authorized to market the existing device; (2) performance data are unnecessary, or if performance data are necessary, well-established methods are available to evaluate the change; and (3) all performance data necessary to support substantial equivalence can be reviewed in a summary or risk analysis format.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of September 28, 2018 (83 FR 49097). FDA revised the guidance as appropriate in response to the comments. This document supersedes the Special 510(k) content in ''The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,'' issued on March 20, 1998.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''The Special 510(k) Program.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''The Special 510(k) Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18008 and complete title of the guidance in the request to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
801	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
''Requests for Feedback and Meetings for Medical Device Submissions: The Q Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: September 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19881 Filed 9–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–XXXX]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services (HHS), is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 12, 2019.

ADDRESSES: Submit your comments to *Sherette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990–XXXX—Subpart C Research Certification Form.

Abstract: Assistant Secretary for Health, Office for Human Research Protections is requesting a new information collection, on the Subpart C Research Certification Form. The purpose of the IRB Registration Form is to provide a simplified, standardized procedure for institutions to submit subpart C research certifications to OHRP in order to obtain authorization to include prisoners in human subjects research as required in 45 CFR 46.305(c).

Likely Respondents: Institutions or Organizations operating IRBs that have enrolled or are planning to enroll prisoners in human subject research conducted or supported by HHS.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Form name	Number of respondents	Average burden per response (in hours)	Total burden hours
Subpart C Certification Form	80	1	80
Total			80

Terry Clark,

Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2019–19857 Filed 9–12–19; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2019–0748]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0028

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0028, Course Approval and Records for Merchant Marine Training Schools; without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before November 12, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2019–0748] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–612), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202–475–3532, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

In response to your comments, we may revise the this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2019–0748], and must be received by November 12, 2019.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://*