assistance (no script), with a decrease of 106 burden hours.

These adjustments result in a decrease of 55,994 burden hours.

CDC requested a total of 38,817 respondents and 29,388 burden hours annually. The respondents to these information collections are travelers and ship medical personnel. There is no cost to respondents other than the time required to provide the information requested.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in minutes)	Total burden hours
Traveler	Airline Travel Illness or Death Investigation Form.	1,800	1	5/60	150
Ship Medical Personnel	Maritime Conveyance Illness or Death Investigation Form.	750	1	5/60	63
Traveler	Land Travel Illness or Death Investigation Form.	100	1	5/60	8
Traveler	Ebola Risk Assessment Form (Ill traveler interview: English, French, Arabic, or other as needed).	100	1	15/60	25
Traveler	United States Traveler Health Declaration (English: Hard Copy, fillable PDF, electronic portal).	9,000	1	15/60	2250
Traveler	United States Traveler Health Declaration (French translation guide).	8,400	1	15/60	2100
Traveler	United States Traveler Health Declaration (Arabic translation guide).	100	1	15/60	25
Traveler	Ebola Risk Assessment Form (English hard copy).	810	1	15/60	203
Traveler	Ebola Risk Assessment French translation guide.	252	1	15/60	63
Traveler	Ebola Risk Assessment Arabic translation guide.	5	1	15/60	1
Traveler	IVR Active Monitoring Survey (English: Recorded).	9,000	21	4/60	12,600
Traveler	IVR Active Monitoring Survey (French: Recorded).	8,400	21	4/60	11,760
Traveler	IVR Active Monitoring: Arabic translation assistance (no script).	100	21	4/60	140
Total		38,817			29,388

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015–31742 Filed 12–16–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act

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: Fax written comments on the collection of information by January 19, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0734. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance for Industry on Safety Labeling Changes—Implementation of Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act, OMB Control Number 0910–0734—Extension

Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(o)(4)) authorizes FDA to require, and if necessary, order labeling changes if FDA becomes aware of new safety information that FDA believes should be included in the labeling of certain prescription drug and biological products approved under section 505 of the FD&C Act or section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(4) of the FD&C Act applies to prescription

drug products with an approved new drug application (NDA) under section 505(b) of the FD&C Act, biological products with an approved biologics license application under section 351 of the PHS Act, or prescription drug products with an approved abbreviated new drug application under section 505(j) of the FD&C Act if the reference listed drug with an approved NDA is not currently marketed. Section 505(o)(4) imposes timeframes for application holders to submit and FDA staff to review such changes, and gives FDA new enforcement tools to bring about timely and appropriate labeling changes. The guidance provides information on the implementation of the new provisions, including a description of the types of safety labeling changes that ordinarily might be required under the new legislation, how FDA plans to determine what constitutes new safety information, the procedures involved in requiring safety labeling changes, and enforcement of the requirements for safety labeling changes.

FDA requires safety labeling changes by sending a notification letter to the application holder. Under section 505(o)(4)(B), the application holder must respond to FDA's notification by submitting a labeling supplement or notifying FDA that the applicant does not believe the labeling change is warranted and submitting a statement detailing the reasons why the application holder does not believe a change is warranted (a rebuttal statement).

Based on FDA's experience to date with safety labeling changes requirements under section 505(o)(4), we estimate that approximately 42 application holders will elect to submit approximately one rebuttal statement each year and that each rebuttal statement will take approximately 6 hours to prepare.

In addition, in the guidance, FDA states that new labeling prepared in response to a safety labeling change notification should be available on the application holder's Web site within 10 calendar days of approval. FDA estimates that approximately 407 application holders will post new labeling one time each year in response to a safety labeling change notification and that the posting of the labeling will take approximately 4 hours to prepare.

In the **Federal Register** of September 2, 2015 (80 FR 53161), 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 BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Rebuttal statement	42	1	42	6	252

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Type of submission	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Posting approved labeling on application holder's Web site	407	1	407	4	1,628

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

Dated: December 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31696 Filed 12–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0226]

Medical Device ISO 13485:2003 Voluntary Audit Report Pilot Program; Termination of Pilot Program; Announcement of the Medical Device Single Audit Program Operational Phase

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Medical Device ISO Voluntary Audit Report Pilot Program. This program allowed the submission of ISO audit reports performed by third parties, along with audit reports from the preceding 2 years, to determine if the owner or operator of the medical device establishment could be removed from FDA's routine inspection work plan for 1 year. FDA is also announcing its participation in the operational phase of the Medical Device Single Audit Program (MDSAP), which will allow third parties recognized by the MDSAP consortium to submit audit reports that FDA will utilize for routine inspections.

DATES: This notice is effective March 31, 2016.

FOR FURTHER INFORMATION CONTACT: Robert Ruff, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3615, Silver Spring, MD 20993–0002, 301–796–6556.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 19, 2012 (77 FR 16036), FDA announced the availability of a final guidance entitled ''Guidance for Industry, Third Parties and Food and Drug Administration Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program'' (Ref. 1). This guidance document was effective on June 5, 2012, and as stated in the guidance was an interim measure while developing a single audit program, to implement section 228 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), which amended section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(7)). The pilot allowed the owner or operator of the medical device