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

establishment to be removed from FDA's routine inspection work plan for 1 year from the last day of the ISO 13485:2003 audit. The voluntary submitted ISO 13485:2003 audit report provides FDA some information on the conformance of the manufacturer with basic and fundamental quality management system requirements for medical devices.

In 2012, FDA started working on the MDSAP with other global regulators within the International Medical Device Regulators Forum (IMDRF) for purposes of leveraging work performed for other medical device regulators to meet its inspection obligations. On November 15, 2013 (78 FR 68853), FDA announced its participation within the MDSAP consortium's pilot program, which is effective January 1, 2014, through December 31, 2016.

After review of the MDSAP Mid-Pilot Report, which published in August 2015 (Ref. 2), FDA announced that it will participate with the other MDSAP Consortium regulators from Australia, Brazil, Canada, and Japan in the implementation of the operational phase of the program starting January 1, 2017. The MDSAP program provides FDA better assurances than the ISO 13485:2003 Voluntary Audit Report Submission Pilot because FDA's requirements under 21 CFR 820 or other FDA regulations typically covered during FDA inspections are encompassed within the MDSAP audit model.

On January 1, 2017, MDSAP will become fully operational to include opening applications for additional auditing organizations beyond the limited eligible auditing organizations within the pilot phase. Each regulator within the consortium has committed to continuing to utilize the MDSAP audits during the pilot as well as during the operational phase as described in the MDSAP public announcements posted on FDA's Web page (Ref. 3).

Also, Health Canada in a recent announcement laid out the timeframe for which they will terminate their Canadian Medical Device Conformity Assessment System (CMDCAS) program and utilize MDSAP as the means by which manufacturers will obtain a medical device license for distribution of medical devices in Canada (Ref. 4). As a result of the implementation of the MDSAP program, FDA will no longer accept ISO 13485:2003 Voluntary Audit Report Submissions after March 31, 2016, to assist transitioning manufacturers over to MDSAP.

II. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov*. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, Guidance for Industry, Third Parties and Food and Drug Administration Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Pilot Program, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM212798.pdf*.

2. Medical Device Single Audit Program (MDSAP) Mid-Pilot Status Report, January 2014–December 2016, available *http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM461661.pdf*.

3. Medical Device Single Audit Program (MDSAP) Pilot, available at *http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/*.

4. Health Canada's transition strategy from CMDCAS to MDSAP, available at *http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/index-eng.php*.

Dated: December 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31692 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–2015–N–0001]

The Twentieth Food and Drug Administration International Separation Science Society Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products—WCBP 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the International Separation Science Society (CASSS), is announcing a meeting entitled ''The Twentieth FDA CASSS Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products—WCBP 2016.'' The purpose of the meeting is to discuss development of biotechnology-derived drug products and analytic methodologies for the development of biotechnology-derived drug products.

DATES: The meeting will be held January 26, 2016, from 8 a.m., until January 28, 2016, at 5 p.m.

ADDRESSES: The meeting will be held at The Mayflower Hotel, 1127 Connecticut Ave. NW., Washington, DC

FOR FURTHER INFORMATION CONTACT: Linda Mansouria, CASSS, 5900 Hollis St., Suite R3, Emeryville, CA 94608, 510–428–0740, FAX: 510–428–0741, *lmansouria@casss.org.*

SUPPLEMENTARY INFORMATION:

I. Background

CASSS is a scientific society providing forums for the dissemination of information and discussions among industry, academic and regulatory professionals founded on the development and applications of separation science. This cosponsored meeting provides state-of-the-art presentations on the technologies used to produce and assess product quality of biotechnology-derived drug products.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this meeting. The registration fee is charged to help defray the costs of programming and facilities. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete registration online at *http://www.casss.org/?WCBP1600.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives.	$1995 (early bird); $2395 (onsite).
Academic	$795 (early bird); $895 (onsite).
Government	$795 (early bird); $895 (onsite).

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Mayflower Hotel in Washington DC are eligible for a reduced rate of $295 USD, not including applicable taxes. To receive the reduced rate, contact the Mayflower