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

Hotel (1–877–212–5752) and identify yourself as an attendee of ''CASSS—WCBP 2016.'' If you need special accommodations due to a disability, please contact Linda Mansouria (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

III. Transcripts

We expect that transcripts will be available approximately 30 days after the meeting. A transcript will be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: December 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–31691 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–D–4562]

Safety Assessment for Investigational New Drug Application Safety Reporting; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry entitled ''Safety Assessment for IND Safety Reporting.'' The draft guidance provides recommendations to sponsors on developing a systematic approach to investigational new drug application (IND) safety reporting for human drugs and biological products developed under an IND. This draft guidance is a follow-on to the guidance for industry and investigators entitled ''Safety Reporting Requirements for INDs and BA/BE Studies'' that provides recommendations for how sponsors of INDs can identify and evaluate important safety information that must be submitted to FDA and all participating investigators, including a recommendation that sponsors develop a safety assessment committee.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 16, 2016. Submit comments on the information collection issues under the Paperwork Reduction Act of 1995 by February 16, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–4562 for ''Safety Assessment for Investigational New Drug Application Safety Reporting; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov*. All comments should be identified with the title ''Safety Assessment for IND Safety Reporting.''

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food