

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

(4) You may view this service information at FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on February 8, 2016.

**Michael Kaszycki,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 1, 11, 16, and 111

[Docket No. FDA-2015-N-0797]

RIN 0910-AG64 and 0910-AG66

#### The Food and Drug Administration Food Safety Modernization Act: Prevention-Oriented Import System Regulations and Implementation; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing a public meeting entitled “FDA Food Safety Modernization Act: Prevention-Oriented Import System Regulations and Implementation.” The public meeting will provide importers and other interested persons an opportunity to discuss import safety regulations and programs, including final rules for foreign supplier verification programs (FSVPs) for importers of food for humans and animals (the FSVP final rule) and accreditation of third-party certification bodies (the third-party certification final rule). Participants will also be briefed on the status of FDA’s Voluntary Qualified Importer Program (VQIP), which is still in development. Additionally, the public meeting will provide importers and other interested

persons an opportunity to discuss FDA’s comprehensive planning effort for the next phase of the FDA Food Safety Modernization Act implementation relating to import safety programs, which includes establishing the operational framework for these programs and plans for guidance documents, training, education, and technical assistance.

**DATES:** See section III, “How to Participate in the Public Meeting” in the **SUPPLEMENTARY INFORMATION** section of this document for dates and times of the public meeting, closing dates for advance registration, and requesting special accommodations due to disability.

**ADDRESSES:** See section III, “How to Participate in the Public Meeting” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** For questions about registering for the meeting, or to register by phone: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: [ctreece@planningprofessionals.com](mailto:ctreece@planningprofessionals.com).

For general questions about the meeting or for special accommodations due to a disability: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: [Juanita.yates@fda.hhs.gov](mailto:Juanita.yates@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things, FSMA directs FDA to issue regulations requiring preventive controls for human food and animal food, setting standards for produce safety, and requiring importers to perform certain activities to help ensure that the food they bring into the United States is produced in a manner consistent with U.S. safety standards.

In the **Federal Register** of November 27, 2015, we published the FSVP final rule (80 FR 74225) and the third-party certification final rule (80 FR 74569).

The FSVP final rule requires importers of food to verify that their

foreign suppliers use processes and procedures that provide the same level of public health protection as the preventive controls and produce safety regulations, where applicable, and also to verify that the food they import is not adulterated and is not misbranded with respect to food allergen labeling.

The third-party certification final rule adopts regulations to provide for accreditation of third-party certification bodies to conduct food safety audits of foreign entities, including registered foreign food facilities, and to issue food and facility certifications under FSMA. Certification will be required to establish VQIP eligibility. To prevent potentially harmful food from reaching U.S. consumers, in specific circumstances FDA also may require a food offered for import to be accompanied by a certification.

On June 5, 2015, we published a notice of availability of a draft guidance for industry on VQIP for importers of human or animal food (80 FR 32136). The draft guidance describes and answers questions about VQIP. To ensure that we consider comments on the draft guidance before we complete a final version of the guidance, we invited electronic or written comments on the draft guidance by August 19, 2015.

The FSVP and third-party certification final rules and related fact sheets are available on FDA’s FSMA Web page located at <http://www.fda.gov/FSMA>.

The FSVP and third-party certification final rules are two of several final rules that will establish the foundation of, and central framework for, the modern food safety system envisioned by Congress in FSMA.

##### II. Purpose and Format of the Public Meeting

FDA is holding the public meeting on FSMA’s prevention-oriented import system to brief participants on the key components of the FSVP and third-party certification final rules; brief participants on the status of the VQIP; discuss the plans for guidance documents related to import safety, as well as training, education, and technical assistance; provide an update on the development of a risk-based industry oversight framework that are at the core of FSMA; and answer questions about these import programs.

The public meeting is an opportunity for FDA to share its current thinking on implementation plans for programs related to import safety. We encourage interested persons to provide feedback during the meeting on any ideas that we present at the public meeting related to the operational aspects of FSMA.

implementation. The agenda and other documents will be accessible on our FSMA Web site at <http://www.fda.gov/FSMA> before the public meeting.

There will be an opportunity for stakeholders who are unable to participate in person to join the meeting via Webcast. (See section III for more information on the Webcast option.)

Following the public meeting, FDA plans to continue dialogue on implementation of these import safety programs with a series of regional meetings across the United States.

**III. How To Participate in the Public Meeting**

We are holding the public meeting on March 21, 2016, from 8:30 a.m. until 5 p.m., at FDA’s Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5100 Paint Branch Parkway, College Park, MD 20740. Due to limited space and time, we encourage all persons who wish to attend the meeting to register in advance. There is no fee to register for the public meeting,

and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to focus their remarks on the implementation or operational aspects of the import safety programs. To make such a presentation, please submit a request and provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment and the limited time available, we are allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be

granted the opportunity to make an oral presentation. We would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

We encourage persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, we will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (*i.e.*, 3-minute oral presentation without visual media).

We encourage interested persons to provide feedback on any ideas that we present at the public meeting related to the operational aspects of FSMA implementation.

Table 1 provides information on participation in the public meeting.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING

	Date	Electronic address	Address	Other Information
Attend public meeting.	March 21, 2016, from 8:30 a.m. to 5 p.m. ET.	Please preregister at <a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a> .	FDA Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5100 Paint Branch Parkway, College Park, MD 20740.	Registration check-in begins at 8 a.m.
View Webcast .....	March 21, 2016, from 8:30 a.m. to 5 p.m. ET.	Individuals who wish to participate by Webcast are asked to preregister at <a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a> .	.....	The Webcast will have closed captioning.
Preregister .....	Register by March 14, 2016.	Individuals who wish to participate in person are asked to preregister at <a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a> .	We encourage the use of electronic registration, if possible <sup>1</sup> .	There is no registration fee for the public meeting.
Request to make a public comment.	Request by March 7, 2016.	Individuals who wish to make a public comment during the Open Public Comment and Q&A Session are asked to submit request at <a href="http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm">http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm</a> .	.....	
Request special accommodations due to a disability	Request by March 7, 2016.	Juanita Yates, email: <a href="mailto:Juanita.yates@fda.hhs.gov">Juanita.yates@fda.hhs.gov</a> .	See <b>FOR FURTHER INFORMATION CONTACT</b> .	
Submit electronic questions about the FSMA final rules.	.....	Submit questions to the FDA FSMA Technical Assistance Network at <a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm</a> .	.....	For more information about the FDA FSMA Technical Assistance Network, visit <a href="http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm">http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm</a> .

<sup>1</sup> You may also register via email, mail, or fax. Please include your name, title, firm name, address, and phone and fax numbers in your registration information and send to: Courtney Treece, Planning Professionals Ltd., 1210 West McDermott St., Suite 111, Allen, TX 75013, 704-258-4983, FAX: 469-854-6992, email: [ctreece@planningprofessionals.com](mailto:ctreece@planningprofessionals.com).

#### IV. Transcripts and Recorded Video

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and at FDA's FSMA Web site at: <http://www.fda.gov/FSMA>. You may also view the transcript at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on FDA's Web site at <http://www.fda.gov>. Additionally, we will be video recording the public meeting. Once the recorded video is available, it will be accessible at FDA's FSMA Web site at <http://www.fda.gov/FSMA>.

Dated: February 23, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1301

[Docket No. DEA-394F]

RIN 1117-AB38

#### Removal of Exemption From Registration for Persons Authorized Under U.S. Nuclear Regulatory Commission or Agreement State Medical Use Licenses or Permits and Administering the Drug Product DaTscan

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** On November 25, 2014, the Drug Enforcement Administration published the interim final rule titled "Exemption from Registration for Persons Authorized Under U.S. Nuclear Regulatory Commission or Agreement State Medical Use Licenses or Permits and Administering the Drug Product DaTscan." The Drug Enforcement Administration is hereby removing this interim final rule as it is no longer needed, as a result of the removal of [<sup>123</sup>I]ioflupane from the schedules of controlled substances effective September 11, 2015.

**DATES:** *Effective Date:* February 26, 2016.

**FOR FURTHER INFORMATION CONTACT:** Barbara J. Boockholdt, Office of

Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

#### SUPPLEMENTARY INFORMATION:

##### Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801-971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and pursuant to 21 U.S.C. 812 (a) and (b), the current list of all scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 822(a)(1), every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by the Attorney General. Further, pursuant to 21 U.S.C. 822(a)(2), every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by the Attorney General.

The Attorney General however may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if the

Attorney General finds it consistent with the public health and safety pursuant to 21 U.S.C. 822(d). The Attorney General delegated this authority to the Administrator of the DEA, 28 CFR 0.100(b), who in turn redelegated that authority to the Deputy Assistant Administrator of the DEA Office of Diversion Control ("Deputy Assistant Administrator"). 28 CFR part 0, subpart R, App. section 7.

##### Background

On November 25, 2014, the DEA published an interim final rule (IFR) exempting from registration persons authorized under Nuclear Regulatory Commission (NRC) or Agreement State Medical Use Licenses or permits and administering the drug product DaTscan directly to patients for diagnostic purposes. 79 FR 70085. The IFR was intended to alleviate the regulatory burdens on those administering the drug product DaTscan, to allow more patients to receive important diagnostic testing. Additionally, because persons who administer DaTscan are subject to strict NRC/Agreement State requirements, the DEA determined in the IFR that the waiver from registration of persons who administer DaTscan was consistent with the public health and safety. The IFR provided an opportunity for interested persons to submit written comments on the rulemaking on or before January 26, 2015.

However, effective September 11, 2015, the DEA removed [<sup>123</sup>I]ioflupane from the schedules of controlled substances. 80 FR 54715. [<sup>123</sup>I]ioflupane is the active pharmaceutical ingredient in DaTscan. Accordingly, a registration exemption is no longer necessary for persons who administer the drug product DaTscan. As the DEA explained in the final rule removing [<sup>123</sup>I]ioflupane from the schedules of controlled substances, all of the administrative, civil, and criminal sanctions applicable to controlled substances no longer apply to those persons who handle [<sup>123</sup>I]ioflupane, or any drug products that contain [<sup>123</sup>I]ioflupane, on or after September 11, 2015.

Because the decontrol of [<sup>123</sup>I]ioflupane supersedes the registration exemption provided in the IFR, the DEA hereby finalizes the rulemaking procedure that was initiated with the November 25, 2014, IFR (79 FR 70085) by publishing this final rule removing that regulation. Below the DEA has provided a discussion of comments received in response to the IFR. 79 FR 70085.