

investigator has presented adequate assurances that the investigator will employ all test articles, and will conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA, solely in compliance with the applicable provisions of this chapter.

Dated: April 7, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Chapter I

[Docket No. FDA-2011-N-0251]

#### **FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities; Public Meeting**

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

**ACTION:** Notice of public meeting; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled “FDA Food Safety Modernization Act: Focus on Preventive Controls for Facilities.” The purpose of the public meeting is to provide interested persons an opportunity to discuss implementation of the preventive controls for facilities provisions of the recently enacted FDA Food Safety Modernization Act (FSMA). FDA is seeking information on preventive controls used by facilities to identify and address hazards associated with specific types of food and specific processes. The public will have an opportunity to provide information and share views that will inform the development of guidance and regulations on preventive controls for food facilities that manufacture, process, pack or hold human food or animal food and feed (including pet food).

**DATES:** See “How to Participate in the Meeting” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Patricia M. Kuntze, Office of External Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5322, Silver Spring, MD 20993, 301-796-8641, [Patricia.Kuntze@fda.hhs.gov](mailto:Patricia.Kuntze@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### **I. Background**

FSMA (Pub. L. 111-353) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation for a modernized, prevention-based food safety system and gives FDA for the first time a legislative mandate to require comprehensive, science-based preventive controls across the food supply.

In particular, section 103 of FSMA requires the owner, operator, or agent in charge of a facility that is required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to take certain preventive actions, including to evaluate the hazards that could affect food manufactured, processed, packed, or held by the facility, and to identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards. FDA is required to develop regulations to establish science-based standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting their implementation.

In addition, FDA is required to issue guidance with respect to hazard analysis and preventive controls. Given the diversity of registered facilities and regulated foods, FDA will use the guidance to assist the food and feed industries in complying with the preventive controls regulations, when they are finalized. FDA will leverage, where appropriate, best practices for hazards and controls identified by industry for specific types of food and feed and specific methods in manufacturing, processing, packing, and holding food and feed. FDA is interested in making appropriate best practices publicly available. FDA is particularly interested in preventive control practices that are applicable and practical for small and very small businesses to implement.

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

If you wish to attend and/or present at the meeting scheduled for April 20, 2011, please register by e-mail at <http://www.blsmmeetings.net/FDAPreventiveControls> by April 15, 2011. FDA is holding the public meeting on section 103 of FSMA to receive input from the public to inform the development of the regulations and guidance identified previously in this document. FDA will also consider input it has received previously through its engagement of stakeholders as part of the process to examine and update current good manufacturing practice requirements and to develop an animal feed safety system.

In general, the meeting format will include introductory presentations by FDA. Listening to our stakeholders is the primary purpose of this meeting. In order to meet this goal, FDA will provide multiple opportunities for individuals to actively express their views by making presentations at the meeting, participating in a total of three 75-minute break-out sessions on the provisions discussed at the meeting, and submitting written comments to the docket within 30 days after this meeting. (Participants can select up to three of the following five break-out sessions: Preventive Controls Guidance, On-Farm Manufacturing and Small Business, Product Testing and Environmental Monitoring, Training and Technical Assistance, and Preventive Controls and the Relationship to cGMPs.) There will be an interactive Webcast; see section III of this document, “How to Participate in the Meeting.” In order to provide Webcast participants with information before and after the meeting, we request attendees provide their name, their affiliation, and email when registering.

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

Stakeholders will have an opportunity to provide oral comments. Due to limited space and time, FDA encourages all persons who wish to attend the meeting, including those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting, to register in advance and to provide the specific topic or issue to be addressed and the approximate desired length of their presentation. Depending on the number of requests for such oral presentations, there may be a need to limit the time of each oral presentation (e.g., 3 minutes each). If time permits, individuals or organizations that did not register in advance may be granted the opportunity for such an oral presentation. FDA would like to maximize the number of stakeholders 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 views at the meeting. FDA anticipates that there will be several opportunities to speak in break-out sessions and an interactive Webcast will also be available for stakeholders who are not onsite.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation through a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the amount of time available and the

approximate time their presentation is scheduled to begin.

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 after all preregistered attendees are seated.

Table 1 of this document provides information on participating in the meeting and on submitting comments to the docket.

TABLE 1—INFORMATION ON PARTICIPATION IN THE MEETING AND SUBMITTING COMMENTS

	Date	Electronic address	Address (non-electronic)	Other information
Date of Public Meeting .....	April 20, 2011, 9 a.m. to 5:30 p.m.	.....	FDA White Oak Campus, The Great Room, Bldg. 31, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993.	Registration begins at 7:30 a.m.
Webcast .....	April 20, 2011, 9 a.m. to 5:30 p.m.	<a href="https://collaboration.fda.gov/preventivecontrols/">https://collaboration.fda.gov/preventivecontrols/</a> .	.....	<ul style="list-style-type: none"> <li>If you have never attended a ConnectPRO meeting: Test your connection: <a href="https://collaboration.fda.gov/common/help/en/support/meeting_test.htm">https://collaboration.fda.gov/common/help/en/support/meeting_test.htm</a>. Get a quick overview: <a href="http://www.adobe.com/go/connectpro_overview">http://www.adobe.com/go/connectpro_overview</a>.<sup>1</sup></li> <li>The webcast will provide closed captioning.</li> </ul>
Advance Registration .....	By April 15, 2011 .....	<a href="http://www.blsmeeings.net/FDAPreventiveControls">http://www.blsmeeings.net/FDAPreventiveControls</a> .	.....	Registration to attend the meeting will also be accepted onsite on the day of the meeting, as space permits. Registration information may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Request special accommodations due to disability.	By April 15, 2011 .....	.....	Patricia M. Kuntze, 301-796-8641, email: <a href="mailto:Patricia.Kuntze@fda.hhs.gov">Patricia.Kuntze@fda.hhs.gov</a> .	
Make a request for oral presentation.	By April 15, 2011 .....	<a href="http://www.blsmeeings.net/FDAPreventiveControls">http://www.blsmeeings.net/FDAPreventiveControls</a> .	.....	Requests made on the day of the meeting to make an oral presentation may be granted as time permits. Information on requests to make an oral presentation may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Provide a brief description of the oral presentation and any written material for the presentation.	By April 15, 2011 .....	<a href="http://www.blsmeeings.net/FDAPreventiveControls">http://www.blsmeeings.net/FDAPreventiveControls</a> .	.....	Written material associated with an oral presentation should be submitted in Microsoft PowerPoint, Microsoft Word, or Adobe Portable Document Format (PDF) and may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided.
Submit electronic or written comments.	Submit comments by May 20, 2011.	Federal eRulemaking Portal: <a href="http://www.regulations.gov">http://www.regulations.gov</a> . Follow the instructions for submitting comments.	FAX: 301-827-6870. Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.	All comments must include the Agency name and the docket number in brackets in the heading of this document. All received comments may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a> , including any personal information provided. FDA encourages the submission of electronic comments by using the Federal eRulemaking Portal. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

<sup>1</sup> Adobe, the Adobe logo, Acrobat and Acrobat Connect are either registered trademarks or trademarks of Adobe Systems Incorporated in the United States and/or other countries.

#### IV. Comments

Regardless of attendance at the public meeting, interested persons may submit to the Division of Dockets Management (see table 1 of this document) either electronic or written comments for consideration at or after the meeting in addition to, or in place of, a request for an opportunity to make an oral presentation. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>. It may be viewed 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. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: April 7, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## DEPARTMENT OF STATE

### 22 CFR Parts 120 and 124

[Public Notice: 7415]

RIN 1400-AC80

#### International Traffic in Arms Regulations: Defense Services

**AGENCY:** Department of State.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of State proposes to amend the International Traffic in Arms Regulations (ITAR) to update the policy regarding defense services, to clarify the scope of activities that are considered a defense service, and to provide definitions of “Organizational-Level Maintenance,” “Intermediate-Level Maintenance,” and “Depot-Level Maintenance,” and to make other conforming changes.

**DATES:** The Department of State will accept comments on this proposed rule until June 13, 2011.

**ADDRESSES:** Interested parties may submit comments within 60 days of the date of the publication by any of the following methods:

- *E-mail:*

*DDTCResponseTeam@state.gov* with the subject line, “Regulatory Changes—Defense Services.”

- *Mail:* PM/DDTC, SA-1, 12th Floor, Directorate of Defense Trade Controls, Office of Defense Trade Controls Policy, ATTN: Regulatory Changes—Defense Services, Bureau of Political Military Affairs, U.S. Department of State, Washington, DC 20522-0112.

- *Internet:* View this notice by searching for its RIN on the U.S. Government regulations Web site at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Director Charles B. Shotwell, Office of Defense Trade Controls Policy, Department of State, Telephone (202) 663-1282 or Fax (202) 261-8199; E-mail *DDTCResponseTeam@state.gov*. ATTN: Regulatory Changes—Defense Services.

**SUPPLEMENTARY INFORMATION:** As part of the President’s Export Control Reform effort, the Department of State is proposing to amend parts 120 and 124 of the ITAR to reflect new policy regarding coverage of defense services.

The Department reviewed the ITAR’s treatment of defense services with a view to enhancing support to allies and friends, improving efficiency in licensing, and reducing unintended consequences. As a result, it was determined that the current definition of defense services in § 120.9 is overly broad, capturing certain forms of assistance or services that do not warrant ITAR control. The proposed change in subpart (a) of the definition of “defense services” narrows the focus of services to furnishing of assistance (including training) using “other than public domain data”, integrating items into defense articles, or training of foreign forces in the employment of defense articles. Consequently, services based solely upon the use of public domain data would not constitute defense services under this part of the definition and, therefore, would not require a license, technical assistance agreement, or manufacturing license agreement to provide to a foreign person. The proposed new definition of defense service also includes a new provision that would control the “integration” of items, whether controlled by the U.S. Munitions List (USML) or the Commerce Control List (CCL), into USML controlled defense

articles even if ITAR-controlled “technical data” is not provided to a foreign person during the provision of such services. Additionally, the new rule specifies that training for foreign “units or forces” will be considered a defense service only if the training involves the employment of a defense article, regardless of whether technical data is involved. This operational definition improves upon the current open-ended wording of § 120.9(a)(3), which covers “military training of foreign units and forces.” Also, significantly, the proposed new rule specifies in subpart (b) examples of activities that do not constitute defense services. For example, the proposed new rule would prevent the anomalous situation where foreign companies are reluctant to hire U.S. citizens for fear that such employment alone constitutes a defense service, even where no technical data would be transferred to the employer.

A new § 120.38 is proposed to provide definitions for “Organizational-Level Maintenance” (or basic level maintenance), “Intermediate-Level Maintenance,” and “Depot-Level Maintenance,” terms used in the proposed revision of § 120.9.

The Department proposes to make several other conforming changes to the ITAR. The proposed rule modifies § 124.1(a), which describes the approval requirements of manufacturing license agreements and technical assistance agreements. The proposed change removes the requirement in § 124.1(a) to seek the Directorate of Defense Trade Controls’ approval if the defense service that is being rendered uses public domain data or data otherwise exempt from ITAR licensing requirements. This change would be made to conform with the revisions made to § 120.9. The Department proposes to delete § 124.2(a), as this requirement is no longer applicable as a result of proposed changes to § 120.9. Conforming changes are to be made to § 124.2(c) to reflect the proposed deletion of § 124.2(a).

This proposed rule was presented to the Defense Trade Advisory Group (DTAG), a Department of State advisory committee, for purposes of comment and evaluation. The DTAG commented favorably on most aspects of this proposed rule, but also recommended certain changes. Having thoroughly reviewed and evaluated the comments and the recommended changes, the Department has determined that it will proceed with the proposed rule per the Department’s evaluation of the written comments and recommendations as follows: