

3. Will not affect intrastate aviation in Alaska; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

#### 2018–01–05 Fokker Services B.V.:

Amendment 39–19146; Docket No. FAA–2017–1182; Product Identifier 2013–NM–093–AD.

#### (a) Effective Date

This AD becomes effective January 22, 2018.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes, certificated in any category, having serial numbers 11268 through 11283 inclusive, 11286, 11289, 11291, 11293, 11295, 11300, 11303, 11306, 11308, 11310, 11312 through 11314 inclusive, 11316, 11318, 11321, 11323 through 11335 inclusive, 11337, 11338, 11340, 11345, 11349, 11352 through 11361 inclusive, 11365 through 11367 inclusive, 11369, 11370, 11372, 11373, 11376 through 11380 inclusive, 11387, 11388, 11391, 11395, 11397, 11399, 11404, 11405, 11407, 11411 through 11419 inclusive, 11425 through 11428 inclusive, 11432, 11435 through 11439 inclusive, 11444 through 11450 inclusive, 11456 through 11460 inclusive, 11464 through 11469 inclusive, and 11475 through 11585 inclusive.

#### (d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

#### (e) Reason

This AD was prompted by an evaluation by the design approval holder (DAH) indicating that the fuselage frames are subject to widespread fatigue damage (WFD). We are issuing this AD to prevent cracking of the

center fuselage, which could result in reduced structural integrity of the airplane.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Required Action(s)

Within 30 days after the effective date of this AD, request instructions from the Manager, International Section, Transport Standards Branch, FAA, to address the unsafe condition specified in paragraph (e) of this AD; and accomplish the actions at the times specified in, and in accordance with, those instructions. Guidance can be found in Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) AD 2013–0102, dated May 2, 2013.

#### (h) Alternative Methods of Compliance (AMOCs)

The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (i)(2) of this AD. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto:9-ANM-116-AMOC-REQUESTS@faa.gov). Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

#### (i) Related Information

(1) Refer to MCAI EASA AD 2013–0102, dated May 2, 2013, for related information. You may examine the MCAI on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–1182.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 1601 Lind Avenue SW, Renton, WA 98057–3356; telephone: 425–227–1137; fax: 425–227–1149.

#### (j) Material Incorporated by Reference

None.

Issued in Renton, Washington, on December 26, 2017.

**John P. Piccola, Jr.,**  
Acting Director, System Oversight Division,  
Aircraft Certification Service.

[FR Doc. 2017–28487 Filed 1–4–18; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 1, 11, 16, 106, 110, 111, 112, 114, 117, 120, 123, 129, 179, 211, and 507**

[Docket No. FDA–2017–N–6908]

### Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs; Guidance for Industry; Availability

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

**ACTION:** Notification of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.” This guidance states agency compliance policy regarding certain entities and/or activities related to the “farm” definition, written assurances, food contact substances, and human food by-products for use as animal food.

**DATES:** The announcement of the guidance is published in the **Federal Register** on January 5, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-N-6908 for “Enforcement Policy for Certain Entities Subject to Requirements in the CGMP and Preventive Controls Regulations, the Produce Safety Regulation, and the Foreign Supplier Verification Programs Regulation.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration (HFS-300), 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

#### FOR FURTHER INFORMATION CONTACT:

*For questions relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Human Food:* Jenny Scott, Center for Food Safety and Applied Nutrition (HFS-300), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2166.

*For questions relating to CGMP, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals:* Jeanette Murphy, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6246.

*For questions relating to Foreign Supplier Verification Programs for Importers of Food for Humans and Animals:* Rebecca Buckner, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4576.

*For questions relating to Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption:* Samir Assar, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1636.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of a guidance for industry entitled “Policy

Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry.” We are issuing the guidance consistent with our good guidance practices regulation (21 CFR 10.115). In accordance with § 10.115(g)(2), we are implementing the guidance immediately because we have determined that prior public participation is not feasible or appropriate. Although the guidance document is immediately in effect, FDA will accept comments at any time. The guidance is not subject to Executive Order 12866.

This guidance document concerns four of the seven foundational rules that we have established in Title 21 of the Code of Federal Regulations (21 CFR) as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353). The four final rules are entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (published in the **Federal Register** of September 17, 2015, 80 FR 55908) (<https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm>) (part 117); “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals” (published in the **Federal Register** of September 17, 2015, 80 FR 51670) (<https://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm>) (part 507); “Foreign Supplier Verification Programs for Importers of Food for Humans and Animals” (published in the **Federal Register** of November 27, 2015, 80 FR 74226) (<https://www.fda.gov/food/guidanceregulation/fsma/ucm361902.htm>) (FSVP regulation); and “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (published in the **Federal Register** of November 27, 2015, 80 FR 74354) (<https://www.fda.gov/food/guidanceregulation/fsma/ucm334114.htm>) (produce safety regulation or part 112).

In the guidance, we state compliance policy for certain entities and/or activities under these four rules:

- Specific facilities subject to part 117 and/or part 507:

- Certain facilities that would qualify as secondary activities farms except for the ownership of the facility (*e.g.*, certain produce packinghouses and warehouses, egg packinghouses, grain elevators, cotton ginners);

- Facilities that would qualify as farms if they did not color RACs;

○ Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity (e.g., dried beans);

○ Farm mixed-type facilities making silage food for animals;

• Written assurances under the “customer provisions” in part 117 and related rules;

• Importation of food contact substances under the FSVP regulation; and

• Certain human food by-products for use as animal food, with regard to certain requirements under part 507.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 117 have been approved under OMB control number 0910–0751. The collections of information in part 507 have been approved under OMB control number 0910–0789. The collections of information in 21 CFR part 1, subpart L, have been approved under OMB control number 0910–0752. The collections of information in part 112 have been approved under OMB control number 0910–0816.

## II. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/FoodGuidances> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: January 2, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–00050 Filed 1–4–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 892

[Docket No. FDA–2017–N–6539]

#### Medical Devices; Radiology Devices; Classification of the Absorbable Perirectal Spacer

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the absorbable perirectal spacer into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the absorbable perirectal spacer’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective January 5, 2018. The classification was applicable on April 1, 2015.

**FOR FURTHER INFORMATION CONTACT:**

Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866, [steven.tjoe@fda.hhs.gov](mailto:steven.tjoe@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Upon request, FDA has classified the absorbable perirectal spacer as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that

does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.