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

§ 39.12 [Amended]
1. The FAA amends § 39.12 by adding the following new airworthiness directive (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, 11305, 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 § 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. 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

(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.

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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.


ADDRESSES: You may submit either electronic or written comments on Agency guidance 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.
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.


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

- 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 gins).
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. 360(k)(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).

The classification will be according to the criteria under section 513(f)(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. 360(c)(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. 360(c)(i)), defining “substantial equivalence.” Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

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.


Leslie Kux,
Associate Commissioner for Policy.

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.

SUPPLEMENTARY INFORMATION:

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.