The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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):

Fokker Services B.V.: Docket No. FAA–2018–0802; Product Identifier 2018–NM–082–AD.

(a) Comments Due Date

We must receive comments by November 13, 2018.

(b) Affected ADs

This AD affects AD 95–21–20, Amendment 39–9407 (60 FR 53857, October 18, 1995) (''AD 95–21–20'').

(c) Applicability

This AD applies to Fokker Services B.V. Model F28 Mark 0070 and 0100, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 49, Airborne auxiliary power.

(e) Reason

This AD was prompted by reports of electrical arcing between the auxiliary power unit (APU) starter motor positive terminal and the APU fuel drain line. We are issuing this AD to address this unsafe condition, which could lead to a fire during APU start and possibly result in damage to the airplane.

(f) Compliance

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

(g) Modification

Within 12 months after the effective date of this AD: Remove the two additional clamps, part number (P/N) MS21919WCH5 and P/N MS21919WCH13, and replace APU fuel drain line P/N D67066–409 with a new APU fuel drain line P/N W67066–401, in accordance with the Accomplishment Instructions of Fokker Service Bulletin SBF100–49–037, dated October 31, 2016.

(h) Terminating Actions for AD 95–21–20

Accomplishing the actions required by paragraph (g) of this AD terminates all requirements of AD 95–21–20.

(i) Parts Installation Prohibition

No person may install APU fuel drain line P/N D67066–409 after modification of an airplane as required by paragraph (g) of this AD.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) 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 (k)(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.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Fokker Services B.V.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2017–0008, dated January 16, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0802.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226.

(3) For service information identified in this AD, contact Fokker Services B.V., Technical Services Dept., P.O. Box 1357, 2130 EL Hoofddorp, the Netherlands; telephone +31 (0)88–6280–350; fax +31 (0)88–6280–111; email *technicalservices@fokker.com;* internet *http://www.myfokkerfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued in Des Moines, Washington, on September 14, 2018.

John P. Piccola,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–20919 Filed 9–27–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2007–N–0465]

Label Requirement for Food That Has Been Refused Admission Into the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the withdrawal of a proposed rule that published in the **Federal Register**. This proposed rule is not currently considered a viable candidate for final action. FDA is taking this action because this proposed rule does not reflect current technology and industry practice.

DATES: The proposed rule published September 18, 2008, at 73 FR 54106 is withdrawn as of September 28, 2018.

ADDRESSES: For access to the docket, 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.

FOR FURTHER INFORMATION CONTACT: Holli Kubicki, Office of Regulatory Affairs, Office of Strategic Planning and Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–4557, *holli.kubicki@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Administration's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or can be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the proposed rule entitled ''Label Requirement for Food That Has Been Refused Admission Into the

United States'' (September 18, 2008, 73 FR 54106).

The proposed rule does not reflect current technology and industry practice. For example, the proposed rule directed owners or consignees to affix labels to physical documents such as invoices, packing lists, bills of lading, and any other documents accompanying refused food. Many of these documents are now electronic. Therefore, since implementation of the proposed rule would not adequately address how to permanently mark electronic documentation accompanying refused food, it would not achieve the public health and efficiency benefits discussed in the notice of proposed rulemaking. As directed by section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353) that was enacted after FDA issued the proposed rule, FDA now requires, as part of its prior notice regulations, notice to FDA of the name of any country to which imported food has been refused entry. (See 21 CFR 1.281(a)(18).) This includes situations where the United States has refused entry, and it therefore provides FDA with information related to what the proposed marking rule would require.

FDA may reassess how to effectively implement the labeling of documentation accompanying refused food and consider whether to issue a revised proposed rule in the future.

The withdrawal of the proposal identified in this document does not preclude the Agency from reinstituting rulemaking concerning the issues addressed. Should we decide to undertake such a rulemaking in the future, we will re-propose the action and provide a new opportunity for comment. Furthermore, this proposed rule withdrawal is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn proposed rule, you may review the Agency's website (*https://www.fda.gov*) for any current information on the matter.

Dated: September 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21145 Filed 9–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket Nos. FDA–2005–N–0033, FDA–2008–N–0115]

Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants; Reporting Information Regarding Falsification of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, we) is announcing the withdrawal of two proposed rules that published in the **Federal Register**. These proposed rules are not currently considered viable candidates for final action. FDA is taking this action because the regulatory requirements set forth in the proposed rules are not needed at this time to protect the public health.

DATES: As of September 28, 2018, the proposed rules published on January 12, 2007, at 72 FR 1582, and February 19, 2010, at 75 FR 7412 are withdrawn.

ADDRESSES: For access to the docket, 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.

FOR FURTHER INFORMATION CONTACT: Brian Pendleton, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4250, Silver Spring, MD 20993–0002, 301–796–4614, *brian.pendleton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1990, FDA began a process of periodically conducting comprehensive reviews of its regulation process, including reviewing the backlog of proposed rulemakings that had not been finalized. As FDA removed many proposed rules not finalized, the Agency implemented a process of reviewing existing proposed rules every 5 years.

As part of this process and the Administration's regulatory reform initiative, we continue to conduct reviews of existing proposed rules. The review determines if the proposals are outdated, unnecessary, or can be revised to reduce regulatory burden while allowing FDA to achieve our public health mission and fulfill statutory obligations.

As part of these efforts, FDA is withdrawing the following proposed rules:

Title of proposed rule	Publication date, **Federal Register** citation	Docket No.	Reason for withdrawal
1. *Use of Materials Derived from Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants.*	January 12, 2007, 72 FR 1582.	FDA–2005–N–0033	We are withdrawing the proposed rule because the risk to public health posed by the potential use of materials derived from cattle in medical products has been significantly diminished since the issuance of the proposed rule, and we believe we can address any potential concerns through application of our premarketing review authority.
2. *Reporting Information Regarding Falsification of Data.*	February 19, 2010, 75 FR 7412.	FDA–2008–N–0115	The rule is not needed to protect research subjects or to help ensure the integrity of clinical trial data submitted to FDA in support of marketing applications and petitions for product approvals. Existing regulations require study sponsors to notify FDA when they end an investigator's participation in an investigation (21 CFR 312.56(b)), and institutional review boards must notify us when they suspend or terminate their approval of research (21 CFR 56.113). Based on our review of recent data, we conclude that we are receiving adequate notice of falsification of data, and we do not believe that adopting the proposed requirements would provide us with substantial additional information.

The withdrawal of the proposed rules does not preclude the Agency from reinstituting rulemaking concerning the issues addressed in the proposed rules listed in the table. Should we decide to undertake such rulemakings in the future, we will re-propose the actions and provide new opportunities for comment. Furthermore, these proposed rules' withdrawal is only intended to address the specific actions identified in this document, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject