(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Reason

This AD was prompted by reports of a disconnect between the elevator lever and control rod. We are issuing this AD to prevent a disconnect between the elevator lever and control rod, which could lead to un-commanded elevator movement of the associated control surface, a large difference between the position of the left and the right elevator control surfaces, and consequent reduced controllability of the airplane and degradation of the structural integrity of the horizontal stabilizer.

(f) Compliance

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

(g) Replacement of Elevator Lever Assemblies and Control Rods

Within 9,200 flight hours or 5 years, whichever occurs first, after the effective date of this AD: Replace the left and right fixed control rods and lever assemblies of the elevator control system with newly designed control rods and lever assemblies, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision C, dated February 13, 2015.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–27–062, dated December 12, 2013; Bombardier Service Bulletin 670BA–27–062, Revision A, dated April 1, 2014; or Bombardier Service Bulletin 670BA–27–062, Revision B, dated October 10, 2014. This service information is not incorporated by reference in this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, New York Aircraft Certification Office (ACO), ANE–170, 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 ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. 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. The AMOC approval letter must specifically reference this AD.

(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, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2014–44, dated December 9, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov/#!documentDetail;D=FAA-2015-0492-0002.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (k)(4) of this AD.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Bombardier Service Bulletin 670BA–27–062, Revision C, dated February 13, 2015.

(ii) Reserved.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514–855–5000; fax: 514–855–7401; email: *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.*

(4) You may view this service information at the 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 August 10, 2015.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–20366 Filed 8–19–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 2 and 157

[Docket No. RM12–11–003; Order No. 790–B]

Revisions to Auxiliary Installations, Replacement Facilities, and Siting and Maintenance Regulations

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule, order on clarification; correction.

SUMMARY: This document contains corrections to the final rule (RM12–11–003) which was published in the **Federal Register** of Friday, July 24, 2015 (80 FR 43944). The final rule amended regulations to: provide pre-granted authority under a new paragraph to abandon or replace auxiliary facilities, subject to certain conditions; permit auxiliary facilities that cannot meet the conditions for the pre-granted abandonment authority in the new paragraph to be abandoned under the blanket certificate regulations, subject to those regulations' requirements; and permit replacement facilities constructed under the regulations to be abandoned under the blanket certificate regulations, subject to those regulations' requirements.

DATES: Effective October 7, 2015.

FOR FURTHER INFORMATION CONTACT:

Katherine Liberty, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6491, *katherine.liberty@ferc.gov.*

Gordon Wagner, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8947, *gordon.wagner@ferc.gov.*

Howard Wheeler, Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–8688, *howard.wheeler@ferc.gov.*

Shannon Jones, Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, (202) 502–6410, *shannon.jones@ferc.gov.*

SUPPLEMENTARY INFORMATION:

Revisions to Auxiliary Installations, Replacement Facilities, and Siting and Maintenance Regulations Docket No. RM12–11–003

Errata Notice

On July 16, 2015, the Commission issued a Final Rule in the above

captioned proceeding. *Revisions to Auxiliary Installations, Replacement Facilities, and Siting and Maintenance Regulations,* 152 FERC ¶ 61,049 (2015). This errata notice makes a correction to the Final Rule as issued.

In FR Doc. 2015–17919 appearing on page 43949 in the **Federal Register** of Friday, July 24, 2015, the following correction is made:

1. On page 43949, in the second column, § 157.216(b)(2)(i)(A) of the regulatory text is revised to read as follows:

''(A) Will not exceed the cost limit in § 157.208(d) for activities under the prior notice provisions;''

Dated: August 14, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–20538 Filed 8–19–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 317

[Docket No. FDA–2008–N–0567]

RIN 0910–AG37

Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorizes the Food and Drug Administration (FDA or Agency) to award priority review vouchers (PRVs) to tropical disease product applicants when the applications meet certain criteria. The FD&C Act lists the diseases that are considered to be tropical diseases for purposes of obtaining PRVs, and also provides for Agency expansion of that list to include other diseases that satisfy the definition of ''tropical diseases'' as set forth in the FD&C Act. FDA has determined that Chagas disease and neurocysticercosis satisfy this definition, and therefore is adding them to the list of designated tropical diseases whose product applications may result in the award of PRVs. Sponsors submitting certain applications for the treatment of Chagas disease and neurocysticercosis may be eligible to receive a PRV if such applications are approved by FDA.

DATES: This order is effective August 20, 2015.

ADDRESSES: Submit electronic comments on additional diseases suggested for designation to *www.regulations.gov.* Submit written comments on additional diseases suggested for designation to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

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I. Background: Priority Review Voucher Program

Much of the global burden of disease falls on populations who lack the resources to develop, encourage development of, or purchase disease preventions or treatments. For this reason, many of the diseases afflicting these populations do not receive the same level of innovation investment as diseases afflicting wealthier or more empowered populations.

Section 524 of the FD&C Act (21 U.S.C. 360n), which was added by section 1102 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), is designed to address the lack of treatment development incentives for such tropical diseases. It uses a PRV incentive to encourage the development of new drugs for prevention and treatment of certain diseases that, in the aggregate, affect millions of people throughout the world. Specifically, section 524 of the FD&C Act defines the term ''tropical disease product application'' and sets forth criteria which, if met, enable those who submit an application for a tropical disease product to be eligible to receive a PRV upon approval of that tropical disease product application. To be eligible for a PRV, the tropical disease product application must meet all of the following criteria:

- The application must be a ''human drug application,'' as defined in section 735(1) of the FD&C Act (21 U.S.C. 379g(1)).
- The application must be for the ''prevention or treatment of a tropical disease,'' as defined by statute.
- The application must be deemed eligible for priority review by the Secretary of HHS.
- The application must be approved after the date of enactment of FDAAA (*i.e.,* September 27, 2007) for use in the prevention, detection, or treatment of a tropical disease.
- The application must be for ''a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 505(b)(1) [21 U.S.C. 355(b)(1)] or section 351 of the [PHS Act].''

Section 524(a)(4) of the FD&C Act. In particular, the requirement that an application must be eligible for priority review demonstrates the PRV program's intent to reward tropical disease product applications that have the potential to demonstrate *significant improvements* in safety or effectiveness in the treatment or prevention of tropical diseases (Ref. 1).

FDA will award a PRV to the application holder upon the approval of a qualifying tropical disease product application that meets the criteria previously listed. The voucher entitles the holder to a priority review of a human drug application, submitted under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act, of the voucher holder's choosing. Once awarded to the application holder, the PRV may be transferred to another entity, and the original holder may receive consideration (including payment) for the transfer. To redeem the voucher, a PRV holder must notify FDA of its intent to use the PRV at least 90 days prior to the submission of the application for which the PRV will be used. This notification constitutes a legally binding agreement to pay the user fee that must be applied to applications using a PRV.

Section 524(a)(3) of the FD&C Act lists the following diseases as tropical diseases qualifying for a PRV:

- Tuberculosis