provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. According to this bilateral airworthiness agreement, the DAC has kept the FAA informed of the situation described above. We have examined the DAC's findings, evaluated all pertinent information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Therefore, we are proposing this AD, which would require modifying the electrical wiring for the stick pusher system. The proposed AD would require you to use the service information described previously to perform these actions.

Costs of Compliance

The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Modification	2	$65	$7	$137	7	$959

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

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):

Empresa Brasileira de Aeronautica S.A. (EMBRAER): Docket No. FAA–2004–19526; Directorate Identifier 2004–NM–140–AD.

Comments Due Date

(a) The Federal Aviation Administration must receive comments on this AD action by December 6, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to EMBRAER Model EMB–135BJ series airplanes, serial numbers 145462, 145495, 145505, 145528, 145625, 145637, and 145642; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report that the stick pushers are not being inhibited when the AP/PUSH/TRIM switches are activated, which can result in reduced controllability of the airplane if there is a system malfunction. We are issuing this AD to prevent reduced controllability of the airplane if the stick pusher system malfunctions.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Modification of Electrical Wiring

(f) Within 400 flight hours or 180 calendar days after the effective date of this AD, whichever is first: Modify the wiring for the stick pusher system by accomplishing all of the actions specified in the Accomplishment Instructions of EMBRAER Service Bulletin 145LEG–27–0009, dated March 1, 2004.

Alternative Methods of Compliance (AMOCs)

(g) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(h) Brazilian airworthiness directive 2004–04–02, dated May 6, 2004, also addresses the subject of this AD.

Issued in Renton, Washington, on October 21, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–24632 Filed 11–3–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2004–19525; Directorate Identifier 2004–NM–18–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200, –200ER, and –300 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Boeing Model 777–200, –200ER, and –300 series airplanes. This proposed AD would require inspection of the outer cylinder of the main landing gear (MLG) to determine the serial number; an ultrasonic inspection of the outer cylinder of the MLG for cracks if necessary; and applicable specified and corrective actions if necessary. This proposed AD is prompted by reports indicating that two outer cylinders were found fractured in the weld area. We are proposing this AD to detect and correct cracks or defects that could result in a fracture of the outer cylinder of the

MLG, which could lead to collapse of the MLG during landing.

DATES: We must receive comments on this proposed AD by December 20, 2004.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, room PL–401, Washington, DC 20590.
- By fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207.

You can examine the contents of this AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, on the plaza level of the Nassif Building, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Gary Oltman, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6443; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION:

Docket Management System (DMS)

The FAA has implemented new procedures for maintaining AD dockets electronically. As of May 17, 2004, new AD actions are posted on DMS and assigned a docket number. We track each action and assign a corresponding directorate identifier. The DMS AD docket number is in the form ''Docket No. FAA–2004–99999.'' The Transport Airplane Directorate identifier is in the form ''Directorate Identifier 2004–NM–999–AD.'' Each DMS AD docket also lists the directorate identifier (''Old Docket Number'') as a cross-reference for searching purposes.

Comments Invited

We invite you to submit any written relevant data, views, or arguments regarding this proposed AD. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2004–19525; Directorate Identifier 2004–NM–18–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments submitted by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to http://dms.dot.gov, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You can review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you can visit *http://dms.dot.gov*.

We are reviewing the writing style we currently use in regulatory documents. We are interested in your comments on whether the style of this document is clear, and your suggestions to improve the clarity of our communications that affect you. You can get more information about plain language at *http://www.faa.gov/language* and *http://www.plainlanguage.gov*.

Examining the Docket

You can examine the AD docket on the Internet at *http://dms.dot.gov*, or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

We have received reports indicating that two outer cylinders of the main landing gear (MLG) were found fractured in the weld area while at the supplier, before delivery to Boeing for installation on Boeing Model 777–200 series airplanes. The outer cylinder of the MLG is a two-piece design, which is welded together on the main barrel. Investigation revealed that the fractured outer cylinders were cleaned with an unapproved cleaning solution before welding. The cleaning solution that was used contained small amounts of oil that may have contaminated the bonding surfaces of the weld, which could cause cracks or defects in the weld. These conditions, if not detected and corrected, could result in a fracture of the outer cylinder of the MLG, which could lead to collapse of the MLG during landing.

Relevant Service Information

We have reviewed Boeing Alert Service Bulletin 777–32A0038, Revision 1, dated February 19, 2004. The service bulletin describes procedures for an ultrasonic inspection for cracks or defects of the outer cylinder of the MLG, applicable specified actions, and corrective actions if necessary. Applicable specified actions may involve jacking up the airplane to remove the MLG, and disassembling the MLG to remove the outer cylinder for the ultrasonic inspection. Corrective actions involve replacing the outer cylinder of the MLG with a new MLG whose part identification numbers are not listed in the service bulletin. The service bulletin also recommends reporting the inspection results to Boeing. Accomplishing the actions specified in the service information is intended to adequately address the unsafe condition.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other airplanes of this same type design. Therefore, we are proposing this AD, which would require inspection of the outer cylinder of the MLG to determine the serial number; an ultrasonic inspection of the outer cylinder of the MLG for cracks if necessary; and applicable specified and corrective actions as necessary. The proposed AD would require you to use the service information described previously to perform these actions, except as discussed under ''Differences Between the Proposed AD and the Service Bulletin.'' The proposed AD would also require that operators send the results of their ultrasonic inspection findings to the FAA only if the inspection finds any crack.

Differences Between the Proposed AD and the Service Bulletin

Unlike the effectivity of the service bulletin, this proposed AD would affect Boeing Model 777–200ER and –300 series airplanes in addition to Model 777–200 series airplanes listed in the service bulletin. We have determined

that, because of the potential for the affected outer cylinders to be installed on all these models, the proposed actions must be done on all of these airplanes to address the identified unsafe condition.

In addition, we have determined that the service bulletin does not completely address the rotability of the affected parts. Therefore, this proposed AD would also require a one-time inspection to determine if a suspect serial number of an outer cylinder may be installed on airplanes other than those listed in the effectivity of the service bulletin.

The service bulletin specifies a compliance time of 8,000 flight cycles or when the outer cylinder is 6 years old, whichever occurs first. We have determined that a grace period of 4,000 flight cycles or 750 days after the effective date of the AD, whichever occurs first, is necessary to prevent unnecessary grounding of airplanes that are over the threshold specified in the service bulletin.

Operators should note that, although the Accomplishment Instructions of the referenced service bulletin describe procedures for submitting a report of all ultrasonic inspection results to the manufacturer, this proposed AD would require submitting the inspection report to the FAA only if the inspection finds any crack. We need further information on the extent of the quality control (QC) problem. When the unsafe condition addressed by an AD is likely due to a manufacturer's QC problem, a reporting requirement is instrumental in ensuring that we can gather as much information as possible regarding the extent and nature of the QC problem or breakdown, especially in cases where such data may not be available through other established means. This information is necessary to ensure that we can apply knowledge and lessons learned from these inspections to future MLG actions. The differences discussed in ''Differences Between the Proposed AD and the Service Bulletin'' have been coordinated with Boeing.

Costs of Compliance

This proposed AD would affect about 463 Model 777 series airplanes worldwide. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per airplane	Number of U.S.-registered airplanes	Fleet cost
Part Number Inspection.	1 to 229 (depending on which inspection method is used).	$65	None	$65 to $14,885	133	$8,645 to $1,979,705.
Ultrasonic Inspection (if necessary).	6	65	None	$390 per outer cylinder, $780 for both outer cylinders on the airplane.	Unknown, there may be up to 26 affected outer cylinders in fleet.	$10,140.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

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):

Boeing: Docket No. FAA–2004–19525; Directorate Identifier 2004–NM–18–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this AD action by December 20, 2004.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all Boeing Model 777–200, –200ER, –300 series airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports that two outer cylinders of the main landing gear (MLG) were found fractured in the weld area. We are issuing this AD to detect and correct cracks or defects that could result in a fracture of the outer cylinder of the MLG, which could lead to collapse of the MLG during landing.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Service Bulletin References

(f) The term ''the service bulletin,'' as used in this AD, means the Accomplishment Instructions of Boeing Alert Service Bulletin 777–32A0038, Revision 1, dated February 19, 2004.

Compliance Time

(g) Perform the applicable actions specified in paragraph (h) of this AD at the later of the times specified in paragraphs (g)(1) and (g)(2) of this AD.

(1) Within 4,000 flight cycles or 750 days after the effective date of this AD, whichever occurs first; or

(2) Before accumulation of 8,000 total flight cycles on the outer cylinder or 72 months on the outer cylinder since new, whichever occurs first.

Part Identification Inspection, Ultrasonic Inspection, and Corrective Action

(h) Inspect the outer cylinder of the MLG to determine whether an outer cylinder having a serial number (S/N) listed in paragraph 1.D., ''Description,'' of the service bulletin is installed. Instead of an inspection of the outer cylinder of the MLG, a review of airplane maintenance records is acceptable if the S/N of the outer cylinder can be positively determined from that review.

(1) If no S/N identified in the service bulletin is installed, no further action is required by this paragraph.

(2) If any S/N identified in the service bulletin is installed, before further flight, do an ultrasonic inspection of the outer cylinder of the MLG for cracks, all applicable specified actions, and any corrective actions per the service bulletin. Do any applicable corrective action before further flight.

Reporting a Crack

(i) Submit a report of any crack is found during the inspection required by paragraph (h)(2) of this AD to the Manager, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue, SW., Renton, Washington, at the applicable time specified in paragraph (i)(1) or (i)(2) of this AD. The report must include the inspection results, a description of any discrepancies found, the outer cylinder serial number and part number, and the number of landings and flight hours on the outer cylinder. Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements contained in this AD and has assigned OMB Control Number 2120–0056.

(1) If the inspection was done after the effective date of this AD: Submit the report within 10 days after the inspection.

(2) If the inspection was accomplished prior to the effective date of this AD: Submit the report within 10 days after the effective date of this AD.

Parts Installation

(j) As of the effective date of this AD, no person may install an outer cylinder having a S/N listed in paragraph 1.D., ''Description,'' of the service bulletin on any airplane unless it has been inspected and all specified and corrective actions are accomplished in accordance with paragraph (h)(2) of this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any action required by this AD, if it is approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on October 21, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–24631 Filed 11–3–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. 2000N–1409]

Medical Devices; Revision of the Identification of the Iontophoresis Device; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the agency issued in the **Federal Register** of August 22, 2000 (65 FR 50949) (the August 2000 proposed rule). In that document, FDA proposed to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. In response to the comments received on the proposed rule, FDA is withdrawing the proposed rule and considering and other courses of action. Elsewhere in this issue of the **Federal Register**, FDA is announcing an opportunity to submit information and comments concerning FDA's intent to initiate a proceeding to reclassify those iontophoresis devices currently in class III into class II (special controls).

DATES: The proposed rule is withdrawn on November 4, 2004.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 23, 1983 (48 FR 53032), FDA issued a final rule classifying the iontophoresis device into class II (performance standards before the Safe Medical Devices Act of 1990 and now special controls) and class III (premarket approval), depending on its intended use. An iontophoresis device is a device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for diagnostic or other uses. If the iontophoresis device is intended for use in the diagnosis of cystic fibrosis or another intended use and the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, the device is categorized as class II. An iontophoresis device that is intended to introduce ions of soluble salts or other drugs into the body for other purposes is categorized as class III.

In the August 2000 proposed rule, FDA proposed regulations to amend the physical medicine devices regulations to remove the class III (premarket approval) iontophoresis device identification. FDA proposed this action because it believed that there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. FDA expected that manufacturers of those devices currently in class III would be able to relabel their devices to meet the class II identification.

II. Withdrawal of the Proposed Rule

FDA received substantial comment in response to the August 2000 proposed rule. Several comments disagreed with FDA's assertion that no class III preamendments iontophoresis devices existed. In response to these comments, FDA is considering other courses of action and is withdrawing the August 2000 proposed rule.

III. Alternative Action

Elsewhere in this issue of the **Federal Register**, FDA is providing interested persons with an opportunity to submit new information concerning the safety and effectiveness of the iontophoresis device. After FDA reviews any information that it receives in response to this notice, the agency will decide whether it should go forward with a reclassification of those iontophoresis devices currently in class III and whether a panel meeting is necessary before taking any action.

Dated: October 25, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–24590 Filed 11–3–04; 8:45 am]

BILLING CODE 4160–01–S