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]

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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]

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