

claims against the former stock form depository institution.

Dated: May 2, 2001.

By the Office of Thrift Supervision.

Ellen Seidman,

Director.

[FR Doc. 01-11573 Filed 5-7-01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000-NE-12-AD; Amendment 39-12218; AD 2001-08-14]

RIN 2120-AA64

Airworthiness Directives: Turbomeca S.A. Arrius Models 2B, 2B1, and 2F Turboshift Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 2001-08-14 applicable to Turbomeca S.A. Arrius models 2B, 2B1, and 2F turboshift engines, that was published in the **Federal Register** on April 26, 2001 (66 FR 20910). The amendment number of 39-12191 used in this AD is incorrect. This document corrects that amendment number. In all other respects, the original document remains the same.

EFFECTIVE DATE: May 31, 2001.

FOR FURTHER INFORMATION CONTACT: James Rosa, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238-7152, fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: A final rule airworthiness directive (FR Doc. 01-10021) applicable to Turbomeca S.A. Arrius models 2B, 2B1, and 2F turboshift engines was published in the **Federal Register** on April 26, 2001 (66 FR 20912). The following correction is needed:

1. On page 20910, in the first column, in the Heading of the document, the docket line is corrected to read “[Docket No. 2000-NE-12-AD; Amendment 39-12218; AD 2001-08-14]”.

PART 39—[CORRECTED]

§ 39.13 [Corrected]

2. On page 20911, in the first column, under amendatory instruction 2, the heading of AD 2001-08-14 is corrected to read as follows:

2001-08-14 Turbomeca S.A. Arrius Models 2B, 2B1, and 2F Turboshift Engines: Amendment 39-12218. Docket No. 2000-NE-12-AD.

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Issued in Burlington, MA, on April 30, 2001.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01-11456 Filed 5-7-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. 98N-0170]

Medical Devices; Medical Device Reporting Regulations; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing Medical Device Reporting (MDR) requirements. When the final regulation was last amended, the regulation published with some errors and omissions that, if uncorrected, may prove to be misleading. This document corrects those errors.

DATES: This rule is effective May 8, 2001.

FOR FURTHER INFORMATION CONTACT: Susan E. Bounds, Center for Devices and Radiological Health (HFZ-500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-2735.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 26, 2000 (65 FR 4112), FDA published a final rule (the January 2000 rule) that amended its MDR regulations governing reporting by manufacturers, importers, distributors, and user facilities of adverse events related to medical devices. These amendments were made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) under the Food and Drug Administration Modernization Act of 1997 (FDAMA). These regulations became effective March 27, 2000. Under certain provisions of FDAMA, reporting requirements for distributors were

eliminated, but reporting requirements for importers, and requirements for distributors to keep records concerning adverse device events and make them available to FDA upon request continue to apply. To accommodate these changes, part 804 (21 CFR part 804) was removed and language was integrated into part 803 (21 CFR part 803) that reflected the retention of importer reporting requirements and recordkeeping requirements for distributors. Another change made by the January 2000 rule revised procedures to require annual, rather than semiannual, summary reporting by user facilities, and eliminated reporting certification requirements. As a result of these substantive amendments, many nonsubstantive changes were made to the organization of provisions in part 803. During preparation of the final rule for publication, however, a number of typographical and editorial errors occurred. In the subsequent months, FDA discovered other errors. The purpose of these amendments is to correct the errors identified in part 803. This document is published as a final rule with the effective date shown above. FDA has determined that this final rule has no substantive impact on the public. FDA, therefore, for good cause, finds under 5 U.S.C.553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

II. Need for Amendments

A. Incorporation of Importer Reporting Requirements Into Part 803

Section 213 of FDAMA eliminated reporting requirements for distributors previously found at part 804. At the same time, reporting requirements for importers were retained and those previously referenced in part 804 were incorporated in part 803. Accordingly, the word “distributor” was removed from applicable paragraphs and the word “importer” was integrated into the text. During preparation of the final rule amending the regulations to incorporate importer requirements, however, the word “importer” was not properly integrated into §§ 803.10, 803.20, 803.50, and 803.52. FDA is amending the regulations to correct this error.

B. Elimination of Reporting Certification and Modification of Semi-Annual Reporting

Section 213(a)(2) of FDAMA revoked section 519(d) of the act (21 U.S.C. 360i(d)) resulting in the elimination of certification requirements. Section 213(c)(1)(A) revised section 519(b)(1)(C) of the act to require annual, rather than