

(ii) Before installing any replacement spar tube that has previously been installed on any helicopter, inspect it IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(2) 1400 or more hours TIS or 30 or more calendar months:

(i) Within 200 hours TIS or 2 calendar months, whichever occurs first, and thereafter at intervals NTE 3000 hours TIS or 72 calendar months, whichever occurs first, inspect the spar tube IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(A) If the spar tube passes the hardness inspection of paragraph 2.B.1.1 of the SB and the scratch, corrosion, and crack inspection of paragraph 2.B.2 of the SB, replace the bushing with a new bushing before further flight.

(B) If the spar tube fails either the hardness inspection of paragraph 2.B.1.1 of the SB or the scratch, corrosion, or crack inspection of paragraph 2.B.2 of the SB, replace the spar tube with an airworthy spar tube before further flight.

(ii) Before installing any replacement spar tube that has previously been installed on any helicopter, inspect it IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(b) For all spar tubes:

(1) With less than 7500 hours TIS or 144 calendar months since original installation:

(i) Prior to accumulating 7500 hours TIS or 144 calendar months, remove the spar tube and inspect IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(ii) After accomplishing the requirements of paragraph (b)(1)(i) of this AD, install an airworthy spar tube before further flight. Before installing any replacement spar tube that has been previously installed in any helicopter, inspect it IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(2) With 7500 or more hours TIS or 144 or more calendar months since original installation:

(i) Within 500 hours TIS or 12 calendar months, whichever occurs first, remove the spar tube and inspect IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(ii) After accomplishing the requirements of paragraph (b)(2)(i) of this AD, install an airworthy spar tube before further flight. Before installing any replacement spar tube that has been previously installed in any helicopter, inspect it IAW the Accomplishment Instructions, paragraph 2.B.1.1 and 2.B.2. of the SB.

(3) After accomplishing the requirements of either paragraph (b)(1) or (b)(2) of this AD, as applicable, thereafter, at intervals NTE 7500 hours TIS or 144 calendar months, whichever occurs first, remove the spar tube and inspect IAW the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2. of the SB.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Regulations Group, Rotorcraft Directorate, FAA.

Operators shall submit their requests through a FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(e) The inspections shall be done in accordance with the Accomplishment Instructions, paragraphs 2.B.1.1 and 2.B.2., in Eurocopter France Service Bulletin No. 01.00.57, Revision 1, dated November 24, 1999. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053-4005, telephone (972) 641-3460, fax (972) 641-3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on November 22, 2000.

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 1999-039-073(A)R1, dated December 29, 1999.

Issued in Fort Worth, Texas, on September 29, 2000.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 00-26235 Filed 10-17-00; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99-NM-228-AD; Amendment 39-11756; AD 2000-11-08]

RIN 2120-AA64

Airworthiness Directives; Boeing Model 747 and 767 Series Airplanes Powered by General Electric Model CF6-80C2 Series Engines; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects a typographical error that appeared in airworthiness directive (AD) 2000-11-08, amendment 39-11756, that was published in the **Federal Register** on June 1, 2000 (65 FR 34935). The

typographical error resulted in a reference to an incorrect fuel specification. That AD is applicable to certain Boeing Model 747 and 767 series airplanes. That AD supersedes an earlier airworthiness directive to require revising the FAA-approved Airplane Flight Manual (AFM) to prohibit the use of certain fuels; and either replacing an existing placard with a new placard, or replacing all dribble flow fuel nozzles (DFFN) with standard fuel nozzles, which terminates the requirements for the new placard and AFM revision. That AD also includes identical requirements applicable to airplanes on which standard fuel nozzles are not installed.

DATES: Effective July 6, 2000.

FOR FURTHER INFORMATION CONTACT: Ed Hormel, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2681; fax (425) 227-1181.

SUPPLEMENTARY INFORMATION: Airworthiness Directive (AD) 2000-11-08, amendment 39-11756, applicable to certain Boeing Model 747 and 767 series airplanes, was published in the **Federal Register** on June 1, 2000 (65 FR 34935). That AD supersedes AD 98-08-23, amendment 39-10472 (63 FR 18817, April 16, 1998) to require revising the FAA-approved Airplane Flight Manual (AFM) to prohibit the use of certain fuels; and either replacing an existing placard with a new placard, or replacing all dribble flow fuel nozzles (DFFN) with standard fuel nozzles, which terminates the requirements for the new placard and AFM revision. That AD also includes identical requirements applicable to airplanes on which standard fuel nozzles are not installed.

As published, AD 2000-11-08 contains an erroneous fuel specification in paragraphs (a)(1)(i) and (c)(1) of that AD. Those paragraphs incorrectly reference MIL-T-83113, which is a specification that does not exist. The correct reference is MIL-T-83133.

Since no other part of the regulatory information has been changed, the final rule is not being republished.

Accordingly, in FR Doc. 00-13447 published June 1, 2000 (65 FR 34935), make the following corrections:

The effective date of this AD remains July 6, 2000.

§ 39.13 [Corrected]

1. On page 34937, in the second column, paragraph (a)(1)(i) of AD 2000-11-08 is corrected to read as follows:
AD 2000-11-08

* * * * *
(a) * * *

(1) * * *

(i) Revise paragraph 1 of the Engine Fuel System section to read as follows: "The fuel designation is General Electric (GE) Specification D50TF2, as revised. Fuel conforming to commercial jet fuel specification ASTM-D-1655, Jet A, and Jet A-1 are authorized for unlimited use in this engine. Fuels conforming to MIL-T-5624 grade JP-5 and MIL-T-83133 grade JP-8 are acceptable alternatives. The engine will operate satisfactorily with any of the foregoing fuels or any mixture thereof." And,

* * * * *

2. On page 34937, in the third column, paragraph (c)(1) of AD 2000-11-08 is corrected to read as follows:

* * * * *

(c) * * *

(1) Revise paragraph 1 of the Engine Fuel System section to read as follows: "The fuel designation is General Electric (GE) Specification D50TF2, as revised. Fuel conforming to commercial jet fuel specification ASTM-D-1655, Jet A, and Jet A-1 are authorized for unlimited use in this engine. Fuels conforming to MIL-T-5624 grade JP-5 and MIL-T-83133 grade JP-8 are acceptable alternatives. The engine will operate satisfactorily with any of the foregoing fuels or any mixture thereof." And,

* * * * *

Issued in Renton, Washington, on October 5, 2000.

Lirio Liu Nelson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00-26237 Filed 10-17-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 98N-0970]

Medical Devices; Labeling for Menstrual Tampon for the "Ultra" Absorbency

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that amends its menstrual tampon labeling regulation to add the term "ultra" absorbency for tampons that absorb 15 to 18 grams (g) of fluid with the syngyna test. At present, FDA requires standardized terms to be used

for the labeling of a menstrual tampon to indicate its particular absorbency. This rule enables consumers to compare the absorbency of one brand and style of tampon with the absorbency of other brands and styles. FDA is issuing this final rule under the Federal Food, Drug, and Cosmetic Act (the act) to ensure that labeling of menstrual tampons is not misleading. Elsewhere in this issue of the Federal Register, FDA is proposing to change the standardized menstrual tampon term "junior" to "light".

DATES: This rule is effective January 16, 2001.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 26, 1989 (54 FR 43766), FDA published a final rule which, among other things, amended its menstrual tampon labeling regulation to standardize the existing absorbency terms ("junior", "regular", "super", and "super plus") to correspond with the following four absorbency ranges: Less than 6 g; 6 to 9 g; 9 to 12 g; and 12 to 15 g of fluid, as measured by the syngyna test. The 1989 final rule did not include terms for tampons with absorbency in the 15 to 18 g range. Tampon manufacturers have asserted that many women need tampons with this higher level of absorbency to manage their heavy menstrual flow. See 54 FR 43766 to 43769.

Tampons are currently classified into class II (special controls) at 21 CFR 884.5460 and 884.5470. Any person who is required to register under section 510 of the act (21 U.S.C. 360) and part 807 (21 CFR part 807) and who intends to begin the introduction or delivery for introduction into interstate commerce of a tampon for commercial distribution is required to submit a premarket notification to FDA at least 90 days before making such introduction or delivery in accordance with section 510(k) of the act and subpart E of part 807. Under § 807.87(e), a 510(k) premarket notification for a menstrual tampon must contain, among other thing, the proposed labeling for the tampon. Section 801.430 (21 CFR 801.430) spells out the specific labeling required for tampons with 15 g or less of absorbency, including standardized terms for absorbency as determined by testing with the specified syngyna methodology. Because the regulation

currently provides no uniform labeling term for tampons that absorb 15 to 18 g of fluid with the syngyna test, the agency is requiring that such tampons be labeled as "ultra" absorbency. FDA has recently cleared a menstrual tampons product in this absorbency range, and they are available to women in the United States. FDA believes that designating a standard term for this absorbency range will improve consumer understanding of tampons across brands and allow for better adherence to advice in the tampon labeling about toxic shock syndrome (TSS).

II. The Proposed Rule

In the Federal Register of January 21, 1999 (64 FR 3255 through 3257), FDA published a proposed rule to add the term "ultra" to describe tampons with a 15 to 18 g absorbency as measured by the syngyna test. The 90-day comment period closed on April 21, 1999.

The agency received nine comments from individuals, tampon manufacturers, one trade association, and one from a member of the U.S. Congress. Besides comments specific to use of the term "ultra", other comments addressed FDA's 1995 draft guidance document on the preparation of 510(k) premarket notifications for menstrual tampons (Ref. 1). Several comments recommended changing the currently used term for tampon absorbency less than 6 g, from "junior" to "light". A summary of the written comments and FDA's response to the comments is provided in section III of this document.

III. Response to Comments

1. Two comments from manufacturers supported the term "ultra". They noted that the term "ultra" is defined in Webster's Dictionary (and others) as "going beyond what is usual or ordinary" and "going beyond others". These comments also noted that menstrual tampons with this absorbency are called "Ultra Plus" in Canada. Comments from two other manufacturers did not favor the term "ultra" for this tampon absorbency. They argued that "ultra" implies the product is more compact in size, more concentrated, more environmentally sound, or possibly superior. The comments noted that "ultra" is a proprietary term carrying one or more of these meanings for a variety of other household products, such as dishwashing detergents and sanitary napkins. These manufacturers proposed the terms "extra" or "extra plus".

FDA concludes that the term "Ultra" is suitable to identify the absorbency of tampons in the range of 15 to 18 g. FDA