

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 Aerospatiale, 316 Route de Bayonne, 31060 Toulouse, Cedex 03, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(h) This amendment becomes effective on July 30, 1997.

Issued in Renton, Washington, on July 7, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97-18202 Filed 7-14-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 94-SW-26-AD; Amendment 39-10077; AD 97-15-04]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron, Inc. Model 214B, 214B-1, and 214ST Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to Bell Helicopter Textron, Inc. (BHTI) Model 214B, 214B-1, and 214ST helicopters, that currently establishes a mandatory retirement life of 60,000 high-power events for the main transmission upper planetary carrier (carrier). This amendment requires changing the method of calculating retirement life for the carrier from high-power events to a maximum accumulated Retirement Index Number (RIN) of 120,000. This amendment is prompted by fatigue analyses and tests that show certain carriers fail sooner than originally anticipated because of the unanticipated high number of lifts or takeoffs (torque events) performed with those carriers in addition to the time-in-service (TIS) accrued under other operating conditions. The actions specified by this AD are intended to prevent fatigue failure of the carrier, which could result in failure of the main transmission and subsequent loss of control of the helicopter.

EFFECTIVE DATE: August 19, 1997.

ADDRESSES: The service information referenced in Note 2 of this AD may be

obtained from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, Texas 76101.

FOR FURTHER INFORMATION CONTACT: Mr. Uday Garadi, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, Fort Worth, Texas 76193-0170, telephone (817) 222-5157, fax (817) 222-5959.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) by superseding AD 94-02-05, Amendment 39-8803 (59 FR 32325, June 23, 1994), which is applicable to BHTI Model 214B, 214B-1, and 214ST helicopters, was published in the **Federal Register** on January 14, 1997 (62 FR 1864). That action proposed to require creation of a component history card or equivalent record using the RIN system and a system for tracking increases to the accumulated RIN, and proposed to establish a retirement life of a maximum of 120,000 accumulated RIN for the carrier.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received on the proposal or the FAA's determination of the cost to the public. The FAA has determined that air safety and the public interest require the adoption of the rule as proposed, with one editorial change. The **ADDRESSES** paragraph in the preamble has been changed to clarify that the service bulletin is not incorporated into the AD, but is mentioned in Note 2 for information only. The FAA has determined that this change will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 11 helicopters of U.S. registry will be affected by this AD, that it will take approximately (1) 48 work hours per helicopter to replace the affected part due to the new method of determining the retirement life required by this AD; (2) 2 work hours per helicopter to create the component history card or equivalent record (record); and (3) 10 work hours per helicopter to maintain the record each year, and that the average labor rate is \$60 per work hour. Required parts will cost approximately \$29,516 per helicopter. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be \$61,813 for the first year and \$60,713 for each subsequent year. These costs assume replacement by the carrier of one-sixth of the fleet each year, creation and maintenance of the records for all the fleet the first year, and creation of one-sixth of the fleet's records and

maintenance of the records for all the fleet each subsequent year.

The regulations adopted herein will not have substantial direct effects 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. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under 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. A final evaluation has been prepared for this action and it is contained in the rules docket. A copy of it may be obtained from the rules docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (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. Section 39.13 is amended by removing Amendment 39-8803 (59 FR 32325, June 23, 1994), and by adding a new airworthiness directive (AD), Amendment 39-10077, to read as follows:

AD 97-15-04 Bell Helicopter Textron, Inc. (BHTI): Amendment 39-10077 Docket No. 94-SW-26-AD. Supersedes AD 94-02-05, Amendment 39-8803.

Applicability: Model 214B, 214B-1, and 214ST helicopters with main transmission upper planetary carrier (carrier), part number (P/N) 214-040-077-007 or -101, installed, certified in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been

modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (e) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required within 25 hours time-in-service (TIS) after the effective date of this AD, unless accomplished previously.

To prevent fatigue failure of the carrier, which could result in failure of the main transmission and subsequent loss of control of the helicopter, accomplish the following:

(a) Create a component history card or equivalent record for the carrier, P/N 214-040-077-007 or -101.

(b) Determine and record the accumulated Retirement Index Number (RIN) to date on the carrier as follows (if the multiplication results in a fraction, round the results up to the next whole number):

(1) For Model 214B or B-1 helicopters:

(i) Multiply the high-power event total to date by 2, or

(ii) If the actual operating hours are *known*, and:

(A) If the type of operation is internal load lift operations only, multiply each operating hour by 7;

(B) If the type of operation involves any external load lift operations and the number of external load lift operations is known, use the table below and multiply the appropriate factor for the average number of external load lift operations by the number of actual operating hours:

Average number of external load lift operations per hour	Factor ¹
0-2.00	7
2.01-5.00	7
5.01-16.00	14
16.01-27.00	21
above 27.00	28

¹ RIN = Factor × Actual Operating Hours.

(C) If the type of operation involves any external load lift operations and the number of external load lift operations is unknown, multiply each actual operating hour by 21; or

(D) If the type of operation is unknown, multiply each actual operating hour by 21.

(iii) If the actual operating hours are *unknown*, assume 900 operating hours per calendar year. Prorate the assumed operating hours for partial years.

(A) If the type of operation is internal only, multiply the assumed operating hours by 7.

(B) If the type of operation involves any external load lift operations and the number of external load lift operations is known, use the table in paragraph (b)(1)(ii)(B) and multiply the appropriate factor for the

average number of external load lift operations by the number of assumed operating hours.

(C) If the type of operation involves any external load lift operations and the number of external load lift operations is unknown, multiply each assumed operating hour by 21.

(D) If the type of operation is unknown, multiply each assumed operating hour by 21.

(2) For Model 214ST helicopters:

(i) Multiply the high-power event total to date by 2, or

(ii) Multiply the factored flight hour total to date by 12.

Note 2: BHTI Alert Service Bulletin (ASB) 214-94-52, which is applicable to Model 214B helicopters, and ASB 214ST-94-66, which is applicable to Model 214ST helicopters, both of which are dated November 7, 1994, pertain to this subject.

(c) After compliance with paragraphs (a) and (b) of this AD, and during each operation thereafter, maintain a count of each lift or takeoff performed and at the end of each day's operations, increase the accumulated RIN on the component history card or equivalent record as follows:

(1) For Model 214B and 214B-1 helicopters,

(i) Increase the RIN by 1 for each takeoff.

(ii) Increase the RIN by 1 for each external load lift operation; or, increase the RIN by 2 for each external load lift operation in which the load is picked up at a higher elevation and released at a lower elevation, and the difference in the elevation between the pick up point and the release point is 200 feet or greater.

(2) For Model 214ST helicopters,

(i) Increase the RIN by 2 for each takeoff.

(ii) Increase the RIN by 2 for each external load lift operation; or, increase the RIN by 4 for each external load lift in which the load is picked up at a higher elevation and released at a lower elevation and the difference in elevation between the pick up point and the release point is 200 feet or greater.

(d) Remove the carrier, P/N's 214-040-077-007 or -101, from service on or before attaining an accumulated RIN of 120,000. The carrier is no longer retired based upon flight hours. This AD revises the Airworthiness Limitations section of the maintenance manual by establishing a new retirement life for the carrier of 120,000 RIN.

(e) 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, Rotorcraft Certification Office, FAA, Rotorcraft Directorate. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Certification Office.

(f) 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.

(g) This amendment becomes effective on August 19, 1997.

Issued in Fort Worth, Texas, on July 8, 1997.

Larry M. Kelly,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97-18499 Filed 7-14-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Lambert-Kay, Division of Carter-Wallace, Inc. The supplemental ANADA provides for oral use 4.54 milligrams per milliliter (mg/mL) pyrantel pamoate suspension in addition to the 2.27 mg/mL product for removal of large roundworms and hookworms in puppies and dogs and to prevent reinfections of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

EFFECTIVE DATE: July 15, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

SUPPLEMENTARY INFORMATION: Lambert-Kay, Division of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512-0181, filed a supplement to ANADA 200-028 that provides for oral use of 4.54 mg/mL of Evict®, Lassie®, and Vet's Own® (pyrantel pamoate) liquid wormer for removal of large roundworms (*T. canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in puppies and dogs and to prevent reinfections of *T. canis* in puppies and adult dogs and in lactating bitches after whelping. The supplemental ANADA provides for use of 4.54 mg/mL pyrantel pamoate suspension in addition to 2.27 mg/mL suspension.

Approval of supplemental ANADA 200-028 for Lambert-Kay's pyrantel