• If the WHEEL N/W STRG FAULT ECAM caution appears, without the L/G SHOCK ABSORBER FAULT ECAM caution:

—No specific crew action is requested by the WHEEL N/W STRG FAULT ECAM caution procedure.

—Refer to the ECAM STATUS.

Note 1: When a statement identical to that in paragraph (h) of this AD has been included in the general revisions of the AFM, the general revisions may be inserted into the AFM, and the copy of this AD may be removed from the AFM.

(i) For airplanes that are not specified in paragraph (g) of this AD: At the times specified in paragraphs (i)(1) and (i)(2) of this AD, perform a boroscope inspection of the NLG upper support (backplate) to detect ruptured (completely broken) anti-rotation lugs, in accordance with Airbus Technical Note 957.1901/05, dated October 18, 2005; and check the NLG strut inflation pressure and adjust as applicable before further flight, according to a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the Direction Générale de l'Aviation Civile (DGAC) (or its delegated agent). Chapter 12, Subject 12–14–32 of the Airbus A318/A319/A320/A321 Aircraft Maintenance Manual (AMM), as revised by Airbus A318/A319/A320/A321 AMM Temporary Revision (TR) 12–001, dated November 13, 2005, is one approved method.

(1) Within 100 flight cycles following an electronic centralized aircraft monitoring (ECAM) caution ''L/G SHOCK ABSORBER FAULT'' associated with at least one of the centralized fault display system (CFDS) messages listed in paragraphs (i)(1)(i), (i)(1)(ii), and (i)(1)(iii) of this AD.

(i) ''N L/G EXT PROX SNSR 24GA TGT POS.''

(ii) ''N L/G EXT PROX SNSR 25GA TGT POS.''

(iii) ''N L/G SHOCK ABSORBER FAULT 2526GM.''

(2) Within 90 days after the effective date of this AD unless accomplished previously in accordance with paragraph (i)(1) of this AD.

(j) If any ruptured (completely broken) upper support anti-rotation lugs are found during the inspections required by paragraph (i) of this AD, before further flight, replace the NLG with a serviceable NLG according to a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the DGAC (or its delegated agent). Chapter 32 of the Airbus A318/A319/A320/A321 AMM is one approved method. If any other damage to the upper support lugs is found, before further flight, check whether the NLG wheels can be turned by hand without the compression of the shock absorber (*i.e.*, without climbing the centering cam with the aircraft NLG on jacks) and the nose wheel steering disconnected from the electrical box 5GC. If the wheels can be turned, before further flight, replace the NLG with a serviceable NLG according to a method approved by either the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the DGAC (or its delegated agent). Chapter 32 of the Airbus A318/A319/A320/A321 AMM is one approved method. If the wheels cannot be turned, within 100 flight cycles accomplish corrective actions (which could include replacement or continuing inspections) in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA.

Alternative Methods of Compliance (AMOCs)

(k)(1) 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.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(l) None.

Material Incorporated by Reference

(m) You must use Airbus Technical Note 957.1901/05, dated October 18, 2005, to perform the actions that are required by this AD, unless the AD specifies otherwise. (The document number of the Airbus technical note is only specified on page 1 of the document.) The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

Issued in Renton, Washington, on November 16, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–23154 Filed 11–22–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–23085; Directorate Identifier 2005–SW–25–AD; Amendment 39–14385; AD 2005–24–05]

RIN 2120–AA64

Airworthiness Directives; Boeing Vertol Model 107–II Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) for Boeing Vertol (Boeing) Model 107–II helicopters. This action requires a visual and magnetic particle inspection of the quill shaft. This amendment is prompted by the discovery of cracks in a quill shaft during a routine inspection. The actions specified in this AD are intended to detect a fatigue crack in a quill shaft and prevent separation of the quill shaft between the aft transmission and the mix box assembly, loss of rotor synchronization, and subsequent loss of control of the helicopter.

DATES: Effective December 8, 2005.

Comments for inclusion in the Rules Docket must be received on or before January 23, 2006.

ADDRESSES: Use one of the following addresses to submit comments on this 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;

• Fax: (202) 493–2251; or

• 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.

You may get the service information identified in this AD from The Boeing Company, c/o Service Engineering, MC P01–10, P.O. Box 16858, Philadelphia, PA 19142–3227.

Examining the Docket

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

FOR FURTHER INFORMATION CONTACT: George Duckett, Aviation Safety Engineer, FAA, New York Aircraft

Certification Office, Airframe and Propulsion Branch, 1600 Stewart Ave., suite 410, Westbury, New York 11590, telephone (516) 228–7325, fax (516) 794–5531.

SUPPLEMENTARY INFORMATION: This amendment adopts a new AD for Boeing Model 107–II helicopters. This action requires a visual and magnetic particle inspection of the quill shaft. This amendment is prompted by the discovery of cracks in a quill shaft during a routine 700-hour TIS clutch replacement in which a magnetic particle inspection of the quill shaft was done. Investigation shows that cracking on the ends of the spline teeth of the quill shaft, around the pinhole, occurs due to a wear step in the mating pinion gear splines. These cracked spline teeth can provide stress concentrations that may lead to fatigue cracks. This condition, if not corrected, could result in separation of the quill shaft between the aft transmission and the mix box assembly, loss of rotor synchronization, and subsequent loss of control of the helicopter.

We have reviewed Boeing Service Bulletin No. 107–63–1005, Revision 1, dated April 27, 2005, which describes procedures for inspections of quill shafts, part number (P/N) 107D2067, all dash numbers. The service bulletin also specifies rejecting any quill shaft with chipped or cracked teeth or any quill shaft with a crack and, although not required by this AD, specifies measuring and recording wear in the spline of the mating pinion gear, P/N 107D2215. Also, Boeing recommends replacing unairworthy quill shafts with airworthy quill shafts, P/N 107D2067–5. These part-numbered quill shafts have been improved with a shot-peen process. However, in this AD, we are only requiring that you replace any unairworthy quill shaft with an airworthy quill shaft with any approved P/N.

This AD is an interim action which covers initial inspections of the quill shaft. We plan to follow this AD with a superseding Notice of Proposed Rulemaking (NPRM) containing longer term requirements. The NPRM will propose adding the pinion gear wear measurements specified in the service bulletin and will propose adding recurring inspections of the quill shaft. Also, because we still have not determined the cause of the wear steps in the mating pinion gear splines, we may consider further rulemaking when the cause is ultimately determined.

This unsafe condition is likely to exist or develop on other helicopters of the same type design. Therefore, this AD is being issued to detect a fatigue crack in a quill shaft and prevent separation of the quill shaft between the aft transmission and the mix box assembly, loss of rotor synchronization, and subsequent loss of control of the helicopter. This AD requires the following for a helicopter with a quill shaft, P/N 107D2067, and a pinion gear, P/N 107D2215, installed:

- Remove the aft transmission assembly, separate the mix box assembly from the aft transmission, and remove the quill shaft from the pinion gear assembly;
- Visually inspect the external spline of the quill shaft for a chipped or cracked tooth around the pinhole; and
- Magnetic particle inspect the quill shaft for a crack.
- Replace any quill shaft that has a crack or a chipped or cracked tooth with an airworthy quill shaft before further flight.

If the pinion gear has 700 or more hours TIS, comply within 50 hours TIS, unless accomplished within the previous 350 hours TIS. If the pinion gear has less than 700 hours TIS, comply on or before reaching 750 hours TIS.

The short compliance time involved is required because these high-usage helicopters can quickly develop pinion gear wear that could lead to cracks in the quill shaft and adversely affect the structural integrity and controllability of the helicopter. Therefore, the actions described previously are required within 50 hours TIS, a short time period of about 2 weeks based on the high usage rate of these model helicopters, and this AD must be issued immediately.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

We estimate that this AD will affect 7 helicopters. We estimate that each helicopter inspection will take about 17 work hours at an average labor rate of $65 per work hour. Required parts will cost $2,500 for each quill shaft. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be $10,235, assuming one quill shaft is replaced on the fleet.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–23085; Directorate Identifier 2005–SW–25–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD. We will consider all comments received by the closing date and may amend the 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 AD. Using the search function of our docket web site, you can find and read the comments to any of our dockets, including the name of the individual who sent the comment. You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will 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 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 an economic evaluation of the estimated costs to comply with this AD. See the DMS to examine the economic evaluation.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with

promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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 adding a new airworthiness directive to read as follows:

2005–24–05 Boeing Vertol (Boeing): Amendment 39–14385. Docket No. FAA–2005–23085; Directorate Identifier 2005–SW–25–AD.

Applicability: Model 107–II helicopters, all serial numbers, with a quill shaft, part number (P/N) 107D2067, all dash numbers, and a spiral bevel pinion gear (pinion gear), P/N 107D2215, installed, certificated in any category.

Compliance: Required as indicated.

To detect a fatigue crack in a quill shaft to prevent separation of the quill shaft between the aft transmission and the mix box assembly, loss of rotor synchronization, and subsequent loss of control of the helicopter, accomplish the following:

(a) For a helicopter with a pinion gear installed with the following hours time-in-service (TIS):

Pinion gear hours TIS	Compliance time
700 or more hours TIS	Within 50 hours TIS, unless accomplished within the previous 350 hours TIS.
Less than 700 hours TIS	On or before reaching 750 hours TIS.

(1) Remove the aft transmission assembly, separate the mix box assembly from the aft transmission, and remove the quill shaft from the pinion gear assembly;

(2) Visually inspect the external spline of the quill shaft for a chipped or cracked tooth around the pinhole; and

(3) Magnetic particle inspect the quill shaft for a crack.

(b) Before further flight, replace any quill shaft that has a crack or a chipped or cracked tooth with an airworthy quill shaft.

Note 1: Boeing Service Bulletin No. 107–63–1005, Revision 1, dated April 27, 2005, pertains to the subject of this AD.

Note 2: Replacement quill shafts manufactured by Kawasaki Heavy Industries (KHI) for use on their Model KV107–II helicopters must be approved by the geographic Aircraft Certification Office (ACO) on a case-by-case basis for installation on a Boeing Model 107–II helicopter.

(c) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, New York ACO, Engine and Propeller Directorate, FAA, for information about previously approved alternative methods of compliance.

(d) Special flight permits will not be issued.

(e) This amendment becomes effective on December 8, 2005.

Issued in Fort Worth, Texas, on November 16, 2005.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 05–23156 Filed 11–22–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 2000N–1663]

RIN 0910–AA61

Investigational New Drugs: Export Requirements for Unapproved New Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on the exportation of investigational new drugs, including biological products. The final rule describes four different mechanisms for exporting an investigational new drug product. These provisions implement changes in FDA's export authority resulting from the FDA Export Reform and Enhancement Act of 1996 and also simplify the existing requirements for exports of investigational new drugs.

DATES: This rule is effective December 23, 2005.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 19, 2002 (67 FR 41642), we (FDA) published a proposed rule to describe various options for exporting an investigational new drug, including a biological product. We issued the proposed rule to implement statutory changes resulting from the FDA Export Reform and Enhancement Act of 1996 (Pub. L. 104–134, as amended by Pub. L. 104–180) and to modify a pre-existing regulatory program for exporting investigational new drugs.

Under current § 312.110(b) (21 CFR 312.110(b)), any person who intends to export an unapproved new drug product for use in a clinical investigation must have either an investigational new drug application (IND) or submit a written request to us (FDA). The written request must provide sufficient information about the drug to satisfy us that the drug is appropriate for investigational use in humans, that the drug will be used for investigational purposes only, and that the drug may be legally used by the consignee in the importing country for the proposed investigational use (see § 312.110(b)(2)(i)). The request must also specify the quantity of the drug to be shipped and the frequency of expected shipments (id.). If we authorize exportation of the drug, we notify the government of the importing country (id.). Similar procedures exist for export requests made by foreign governments (see § 312.110(b)(2)(ii)). Section 312.110(b)(3) states that the requirements in paragraph (b) apply only where the drug is to be used for the purpose of a clinical investigation. Section 312.110(b)(4) states that the requirements in paragraph (b) do not apply to the exports of new drugs approved or authorized for export under