Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent reduced controllability of the airplane, due to problems associated with the elevator aileron computer (ELAC), accomplish the following:

(a) Within 1 year after the effective date of this AD, replace the ELAC's having part numbers (P/N) 3945122307 and/or P/N C12370AAA01 and located in aft electronics rack 80VU, with modified ELAC's having P/N 3945122502, in accordance with Airbus Industrie Service Bulletin A320–27–1082, dated April 25, 1995.

Note 2: Airbus Industrie Service Bulletin A320–27–1082 references Sextant Service Bulletins 394512–27–014, dated August 11, 1995 (for airplanes on which Airbus Industrie modification 24136P3436 has not been installed); and C12370A–27–001, dated May 2, 1995 (for airplanes on which Airbus Industrie modification 24136P3436 has been installed); as additional sources of procedural service information for modification of the ELAC's.

(b) 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, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) 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 airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 31, 1996.

S.R. Miller,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–252 Filed 1–6–97; 8:45 am]

BILLING CODE 4910–13–U

## 14 CFR Part 39

**[Docket No. 96–SW–32–AD]**

## Airworthiness Directives; Hiller Aircraft Corporation Model UH–12A, UH–12B, UH–12C, UH–12D, and UH–12E Helicopters

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the supersedure of an existing airworthiness directive (AD), applicable to Hiller Aircraft Corporation (Hiller) Model UH–12A, UH–12B, UH–12C, UH–12D, and UH–12E helicopters, that currently requires a dye penetrant inspection of the head of the main rotor outboard tension-torsion (T–T) bar pin for cracks; a visual inspection of the outboard T–T bar pin for proper alignment and an adjustment, if necessary; and, installation of shims at the inboard end of the drag strut. This action would require the same actions required by the existing AD, but would allow a magnetic particle inspection of the T–T bar pin as an alternative to the currently required dye penetrant inspection, and would require reporting the results of the inspections only if cracks are found, rather than reporting all results of inspections as required by the existing AD. This proposal is prompted by an FAA analysis of a comment to the existing AD, and the fact that no cracks have been reported since the issuance of the existing AD. The actions specified by the proposed AD are intended to prevent cracks in the head area of the outboard T–T bar pin, which could result in loss of in-plane stability of the main rotor blade and subsequent loss of control of the helicopter.

**DATES:** Comments must be received by March 10, 1997.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–SW–32–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Hiller Aircraft Corporation, 3200 Imjin Road, Marina, California 93933–5101. This information may be examined at the FAA, Office of the Assistant Chief Counsel, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

**FOR FURTHER INFORMATION CONTACT:** Mr. Charles Matheis, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Blvd., Lakewood, California 90712–4137, telephone (310) 627–5235, fax (310) 627–5210.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 96–SW32–AD.'' The postcard will be date stamped and returned to the commenter.

### Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 96–SW–32–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

### Discussion

On May 25, 1995, the FAA issued AD 95–12–02, Amendment 39–9252 (60 FR 30184) to require for Hiller Model UH–12A, UH–12B, UH–12C, UH–12D, and UH–12E helicopters, within 25 hours time-in-service (TIS) or at the next 100 hour inspection, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS: (1) an inspection of the alignment of the outboard T–T bar pin and an adjustment, if necessary; and (2) an inspection for cracks in the head of the outboard T–T bar pin using a dye

penetrant method. Additionally, that AD requires, within 25 hours TIS or at the next 100 hour inspection, whichever occurs first, the installation of shims between the inboard end of the drag strut and the outboard T–T bar pin. That action was prompted by two accidents involving failure of the outboard T–T bar pin on Hiller UH–12E helicopters. The requirements of that AD are intended to prevent cracks in the head area of the outboard T–T bar pin, which could result in loss of in-plane stability of the main rotor blade and subsequent loss of control of the helicopter.

Since the issuance of that AD, the FAA has received a comment suggesting that paragraph (b) of the existing AD should specifically identify the compliance time for the inspection, even though the compliance time is stated in paragraph (a). The FAA agrees with the commenter, and the wording of paragraph (b) has been changed to clarify the inspection compliance time. Additionally, the same commenter requested that an alternate method of compliance for the inspection be included in paragraph (b) of the existing AD. The FAA agrees, and paragraph (b) has been changed to allow the use of a magnetic particle inspection as well as a dye penetrant inspection required by the existing AD. One additional commenter states that misalignment of the drag strut fork and the main rotor blade may be causing cracks. While the cause of the cracks is uncertain, the FAA has determined that the recurring inspections required by this AD should detect misalignments and cracks that could lead to failure of the T–T bar pin.

Since an unsafe condition has been identified that is likely to exist or develop on other Hiller Model UH–12A, UH12B, UH–12C, UH–12D, and UH–12E helicopters of the same type design, the proposed AD would supersede AD 95–12–02 to require, within 25 hours TIS or at the next 100 hour inspection, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS: (1) an inspection of the alignment of the outboard T–T bar pin and an adjustment, if necessary; and (2) an inspection for cracks in the head of the outboard T–T bar pin using a dye penetrant method or a magnetic particle method. Additionally, the proposed AD requires, within 25 hours TIS or at the next 100 hour inspection, whichever occurs first, the installation of shims between the inboard end of the drag strut and the outboard T–T bar pin.

The FAA estimates that 700 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per helicopter to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $700 per pin. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $574,000, assuming one pin must be replaced on every helicopter in the fleet.

The regulations proposed herein would 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed 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) if promulgated, 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 copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting 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.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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 USC 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by removing Amendment 39–9252 (60 FR 30184, June 8, 1995), and by adding a new airworthiness directive (AD), to read as follows:

Hiller Aircraft Corporation: Docket No. 96–SW–32–AD. Supersedes AD 95–12–02, Amendment 39–9252.

*Applicability:* Model UH–12A, UH–12B, UH–12C, UH–12D, and UH–12E helicopters, certificated 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 as indicated, unless accomplished previously.

To prevent cracks in the head area of the outboard tension-torsion (T–T) bar pin, which could result in loss of in-plane stability of the main rotor blade and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 25 hours time-in-service (TIS) after the effective date of this AD, or at the next 100 hour inspection, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS, inspect the alignment of the outboard T–T bar pin, part number (P/N) 51452, and adjust the alignment, if necessary, in accordance with Hiller Aviation Service Letter (SL) 51–2, dated March 31, 1978.

(b) Within 25 hours TIS after the effective date of this AD, or at the next 100 hour inspection, whichever occurs first, and thereafter at intervals not to exceed 100 hours TIS, inspect the head of the outboard T–T bar pin for cracks using a dye penetrant or magnetic particle inspection method.

(c) If a crack is found as a result of the inspection required by paragraph (b) of this AD, report the results within 7 working days following the inspection to the Manager, Los Angeles Aircraft Certification Office, Attention Charles Matheis, ANM–120L, 3960 Paramount Blvd., Lakewood, California 90712–4137. Include the helicopter model number, serial number, and total TIS of the outboard T–T bar pin in the report. Reporting requirements have been approved by the Office of Management and Budget and assigned OMB control number 2120–0056.

(d) Within 25 hours TIS after the effective date of this AD, or at the next 100 hours TIS inspection, whichever occurs first, install shims between the inboard end of the drag strut and the outboard T–T bar pin in accordance with the Accomplishment Instructions of Hiller Aviation Service Bulletin No. 51–9, dated April 8, 1983.

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

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft 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. Issued in Fort Worth, Texas, on December 30, 1996.

Larry M. Kelly,

*Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 97–251 Filed 1–6–97; 8:45 am]

BILLING CODE 4910–13–U

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 812

**[Docket No. 95N–0342]**

## Export Requirements for Medical Devices; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening for 60 days the comment period for a proposed rule that appeared in the Federal Register of November 27, 1995 (60 FR 58308). The document proposed to amend FDA's regulations for investigational devices to streamline requirements for persons seeking to export unapproved medical devices. FDA is seeking comments on whether this rulemaking is still needed in light of recent changes in the export provisions of the Federal Food, Drug, and Cosmetic Act (the act).

**DATES:** Written comments by March 10, 1997.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–827–3380, electronic mail: PChao@bangate.FDA.gov.

**SUPPLEMENTARY INFORMATION:**

I. The National Performance Review and the Proposed Rule on Device Exports

At present, two statutory provisions in the act govern the export of devices that are not approved for marketing in the United States.

The first provision, in section 801(e)(2) of the act (21 U.S.C. 381(e)(2)), became law as part of the Medical Device Amendments Act of 1976 (Pub. L. 94–295) and required FDA approval of certain exports of unapproved devices. The second provision, in section 802 of the act (21 U.S.C. 382), was the result of the FDA Export Reform and Enhancement Act of 1996 (the Export Act of 1996) (Pub. L. 104–134, and amended by Pub. L. 104–180).

Before the latter provision became law, FDA had undertaken a program to streamline the requirements for the exportation of unapproved devices under section 801(e) of the act. In the Federal Register of November 27, 1995 (60 FR 58308), FDA issued a proposed rule to simplify the agency's export approval process for certain unapproved devices. The proposed rule was intended, in part, to respond to concerns in the device industry that the statutory requirement of FDA approval of device exports may undermine a firm's ability to compete in international markets and may represent an unnecessary regulatory barrier. (It should be emphasized, however, that FDA's approval times for device export applications have decreased significantly, from an average of 91 days per request in 1992 to 10 days in 1995, and further decreased to 8 days in fiscal year 1996.)

The proposed rule was also intended to implement part of the President's and Vice-President's ''National Performance Review'' pertaining to the exportation of unapproved devices (as announced in an April 1995 report entitled ''Reinventing Drug and Device Regulations''). Under the National Performance Review, the agency would permit the export of unapproved devices to certain advanced industrialized countries without prior FDA review and approval, provided that the device complied with the importing country's laws. The report also stated that the Administration would seek the necessary legislative changes and would consult Congress on the appropriate list of advanced industrialized countries. Furthermore, the report stated that FDA would initiate administrative changes to permit exports to countries that are not on the list of advanced industrialized countries ''if the exporter has an investigational device exemption (IDE) permitting testing on humans in the United States, the importing country has given FDA a letter providing blanket approval for IDE-type devices, and the device is in compliance with the importing country's laws.''

To implement the administrative reform aspects of the report, FDA proposed to amend § 812.18 (21 CFR 812.18) to state that a person who wishes to export an investigational device subject to part 812—Investigational Device Exemptions (21 CFR part 812) must comply with the requirements in section 801(e)(1) of the act, but that, for purposes of section 801(e)(2), prior FDA approval would be unnecessary if the investigational device to be exported is the subject of an approved IDE (including nonsignificant risk devices which, under FDA regulations, are considered to have an approved IDE) and ''will be marketed or used in clinical trials in the foreign country for the same intended use as that in the approved IDE and is to be exported to a country that has expressed its approval of the importation of investigational devices'' that are the subject of an approved IDE. The proposed rule also stated that, if the device is the subject of an approved IDE and has received a ''CE'' mark from the European Union (EU), the device may be exported to any country in the European Economic Area (EEA).

Proposed § 812.18(b)(1) also would have FDA's Center for Devices and Radiological Health (CDRH) make available a list of countries that have approved the importation of investigational devices that are the subjects of approved IDE's. The list would be maintained electronically.

Proposed § 812.18(b)(2) would require prior FDA approval to export an investigational device if FDA withdrew approval of the IDE or the sponsor terminated any or all parts of investigations because unanticipated adverse device effects present an unreasonable risk to subjects.

In the preamble to the proposed rule, FDA also stated that it would amend the proposed rule to reflect any legislative changes (60 FR 58308 at 58309).

Thus, the changes in the proposed rule would have benefited those companies wishing to export devices: (1) That have an approved U.S. IDE; (2) to countries that have agreed to accept U.S. IDE products; and (3) whose intended use is the same as the U.S. IDE. FDA believed this was as much