and placed in the Rules Docket. A copy of it, if filed, 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, Incorporation by reference, 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:

AD 97–13–09 McDonnell Douglas Helicopter Systems: Amendment 39–10056. Docket No. 96–SW–35–AD.

Applicability: Model MD–900 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 (d) 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 establish a life limit for various parts and reduce the current life limit on other parts, accomplish the following:

(a) Within 100 hours time-in-service (TIS) after the effective date of this AD:

(1) For Model MD–900 helicopters with serial number (S/N) 0002 through 0012, apply serial numbers to the mid-forward truss assembly, P/N 900F2401200–102, and the forward and aft deck-fitting assemblies, P/N 900F2401500–103 and P/N 900F2401600–103.

(2) For Model MD–900 helicopters with S/N 0002 through 0048, apply S/N's to the left and right vertical stabilizer control system (VSCS) bellcrank assemblies, P/N 900F2341712–101 or P/N 900FP341712–103, and the mid-aft truss strut assembly, P/N 900F2401300–103.

(3) Apply the S/N's as specified in paragraphs (a)(1) and (a)(2) of this AD adjacent to the existing P/N's, and in accordance with the Accomplishment Instructions of McDonnell Douglas Helicopter Systems Service Bulletin No. SB900–039, Revision 2, dated March 12, 1997.

(b) Before further flight, remove from service:

(1) The non-rotating swashplate assembly, P/N 900C2010192–105, –107, –109, or –111, on or before attaining 554 hours TIS.

(2) The collective drive link assembly, P/N 900C2010207–101, on or before attaining 1,480 hours TIS.

(3) The self-aligning, spherical/slider main rotor bearing, P/N 900C3010042–103, on or before attaining 480 hours TIS.

(4) The VSCS bellcrank assembly, P/N 900FP341712–103, and bellcrank arm, P/N 900F2341713–101 (used in the VSCS bellcrank assembly, P/N 900F2341712–101), on or before attaining 2,700 hours TIS.

(c) This AD revises the Airworthiness Limitations section of the maintenance manual by establishing new retirement lives for these parts.

(d) 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. 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.

(e) 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.

(f) The modification shall be done in accordance with McDonnell Douglas Helicopter Systems Bulletin No. SB900–039, Revision 2, dated March 12, 1997. 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 McDonnell Douglas Helicopter Systems, Technical Publications, Bldg. 530/B11, 5000 E. McDowell Road, Mesa, Arizona 85205–9797. Copies may be inspected at the FAA, Office of the Assistant Chief Counsel, 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.

(g) This amendment becomes effective on July 10, 1997.

Issued in Fort Worth, Texas, on June 17, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–16568 Filed 6–24–97; 8:45 am]

BILLING CODE 4910–13–U

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

Alternative Method of Compliance With Requirements for Delivery and Retention of Monthly, Confirmation and Purchase-and-Sale Statements; Correction

AGENCY: Commodity Futures Trading Commission.

ACTION: Correction to an Advisory.

SUMMARY: This document contains a correction to the Advisory that was published on Tuesday, June 10, 1997 (62 FR 31507). The Advisory related to delivery by futures commission merchants (''FCMs'') of confirmation, purchase-and-sale and monthly statements by means of electronic media and related recordkeeping requirements. The correction clarifies potential confusion in connection with the Commodity Futures Trading Commission's (''Commission's'') definition of ''eligible customer'' for purposes of the Advisory.

EFFECTIVE DATE: June 25, 1997.

FOR FURTHER INFORMATION CONTACT: Susan C. Ervin, Deputy Director/Chief Counsel; Lawrence B. Patent, Associate Chief Counsel; or Natalie A. Markman, Attorney-Advisor, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, N.W., Washington, DC 20581. Telephone: (202) 418–5450.

SUPPLEMENTARY INFORMATION: On June 10, 1997, the Commission published an Advisory issuing guidance to FCMs concerning alternative methods of compliance by FCMs with requirements in Commission Rules 1.33 and 1.46 pertaining to the delivery of specified customer account documents and requirements for recordkeeping in Commission Rule 1.31. The Commission defined an ''eligible customer,'' for purposes of the Advisory, to include any person who is an ''institutional customer,'' as ''currently'' defined by Federal Reserve Board (''FRB'') Rule 225.2(g).[1] The Advisory included a list of the persons included in the Rule

[1] 12 CFR 225.2(g) (1996).

225.2(g) definition [2] but, in an effort to eliminate any possible confusion, the Commission makes the following correction: In the **Federal Register** published June 10, 1997, on page 31509, in the third column, in paragraph (2), replace ''as currently defined by FRB Rule 225.2(g)'' with ''as defined by FRB Rule 225.2(g) on April 20, 1997.''

Issued in Washington, D.C. on June 20, 1997 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–16625 Filed 6–24–97; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 314, and 600

[Docket No. 96N–0108]

Postmarketing Expedited Adverse Experience Reporting for Human Drug and Licensed Biological Products; Increased Frequency Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on expedited reporting of postmarketing adverse experiences to revoke the requirement for increased frequency reports as expedited reports for human drug and licensed biological products. This action, which is part of the President's regulatory reinvention initiative, is based on FDA's determination that expedited increased frequency reports have not contributed to the timely identification of safety problems requiring regulatory action and are no longer necessary for FDA surveillance of postmarketing adverse experiences. This action is intended to streamline postmarketing expedited reporting of adverse experiences for human drug and licensed biological products. This action will not affect the requirement for expedited reporting of all serious, unexpected adverse experiences.

EFFECTIVE DATE: July 25, 1997.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Audrey A. Thomas, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5625.

For information concerning human licensed biological products: Marcel E. Salive, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, suite 200S, Rockville, MD 20852–1448, 301–827–3974.

SUPPLEMENTARY INFORMATION:

I. Background

Under current §§ 310.305(c)(4), 314.80(c)(1)(ii) and (c)(1)(iii), and 600.80(c)(1)(ii) and (c)(1)(iii) (21 CFR 310.305(c)(4), 314.80(c)(1)(ii) and (c)(1)(iii), and 600.80(c)(1)(ii) and (c)(1)(iii)), applicants, manufacturers, packers, and distributors, including licensed manufacturers and other manufacturers of biological products, are required to review periodically the frequency of reports of adverse experiences that are both serious and expected and reports of therapeutic failure (lack of effect), regardless of source, and report any significant increase in frequency as soon as possible but in any case within 15 working days of determining that a significant increase in frequency exists. An increased frequency exists if the adjusted reporting for the reporting interval is at least two times greater than the adjusted reporting for the comparison interval (previous reporting interval). These regulations were issued by FDA to ensure that applicants, manufacturers, packers, and distributors, including licensed manufacturers and other manufacturers of biological products, identify increases in the incidence of serious, labeled adverse experiences that are not anticipated from premarketing clinical trials and that occur with changes in medical practice, such as using a drug or biological product in higher risk populations, at higher dosages, or concomitantly with other drugs or biological products causing interactions.

In the **Federal Register** of October 28, 1996 (61 FR 55602), FDA proposed to amend its postmarketing expedited adverse experience reporting regulations to revoke the requirement for expedited increased frequency reports in §§ 310.305(c)(4), 314.80(c)(1)(ii) and (c)(1)(iii), and 600.80(c)(1)(ii) and (c)(1)(iii), and to revoke the definition of ''increased frequency'' in §§ 310.305(b)(5), 314.80(a), and 600.80(a). As explained in the proposal, FDA determined that increased frequency reports rarely prompted regulatory action during the time that the agency received such reports, and the reports proved to be of little value in identifying increased incidences of serious, labeled experiences. This action does not affect the requirement for expedited reporting of all serious, unexpected adverse experiences. Applicants, manufacturers, packers, and distributors, including licensed manufacturers and other manufacturers of biological products, must continue to submit 15-day Alert reports and followup reports for serious, unexpected events, as required under §§ 310.305(c), 314.80(c), 314.98, and 600.80(c).

II. Rationale

Several factors have contributed to FDA's decision to revoke the requirement for expedited increased frequency reports. Key factors include: (1) Safety problems that have been the subject of these reports could have been detected in other safety reports, (2) the reliability of increased frequency reports is limited, and (3) this action is consistent with recent international efforts to harmonize reporting requirements. These factors are discussed in more detail in the following paragraphs.

Only a small number of drug/biological product safety problems where expedited increased frequency reports played a role in risk assessment have resulted in regulatory action. In each case, the safety problems could have been detected in other safety reports required by FDA such as periodic adverse experience reports, field alert reports, or annual reports. FDA has found that expedited postmarketing adverse experience reporting systems are best used to identify rare, unexpected adverse drug reactions such as aplastic anemia, hepatic necrosis, renal failure, or anaphylaxis that were not detected in preclinical studies or clinical trials during drug development.

The reliability of increased frequency reports is limited because of the difficulty in accurately estimating incidence rates. Increased frequency information is derived from incidence rates, which are estimated by dividing

[2] The following were ''institutional customers'' under the FRB rule:

(1) a bank (acting in an individual or fiduciary capacity), savings and loan association, insurance company, investment company registered under the ICA, or corporation, partnership, proprietorship, organization or institutional entity with a net worth exceeding $1,000,000;

(2) an employee benefit plan with assets exceeding $1,000,000, or whose investment decisions are made by a bank, insurance company or investment adviser registered under the Investment Advisers Act of 1940;

(3) a natural person whose net worth (or joint net worth with a spouse) exceeds $1,000,000;

(4) a broker-dealer or option trader registered under the SEA, or other securities, investment or banking professional; or

(5) an entity whose equity owners are institutional customers.