the regulatory docket. A copy of it may be obtained from the Regional Rules Docket.

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 § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by amending Amendment 39-6112 (54 FR 1338; January 13, 1989), AD 89-02-07, by revising the paragraph after the compliance statement and paragraph (a) as follows:

Bell Helicopter Textron, Inc. (BHTI): Applies to Bell Model 204B, 205A, 205A-1, and 212 helicopters certificated in any category. [Airworthiness Docket No. 87-ASW-63]

* * * * *

To prevent possible fatigue failure of main rotor masts, P/N 204-011-450-007, -105 and main rotor trunnion, P/N 204-011-105-001, which could result in a catastrophic failure of the main rotor system and subsequent loss of the helicopter, accomplish the following:

(a) Within 10 days after the effective date of this AD, create a historical service record for main rotor masts, P/N 204-011-450-007 and -105 and main rotor trunnion, P/N 204-011-105-001, and record the time in service accumulated on the main rotor mast and trunnion. If the time in service cannot be determined, enter 900 hours for each year from the date the mast and trunnion were installed.

* * * * *

This amendment becomes effective October 31, 1989.

This amendment amends Amendment 39-6112, (54 FR 1338; January 13, 1989), AD 89-02-07.

Issued in Fort Worth, Texas, on September 19, 1989.

James D. Erickson,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 89-23132 Filed 9-29-89; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 88-ASW-43; Amdt. 39-6341]

Airworthiness Directives; McDonnell Douglas Helicopter Company (MDHC) Model 369D, E, F, and FF Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends an airworthiness directive (AD) which requires repetitive inspections of main rotor blade retention strap (strap pack) laminates for cracks and failures; recording of the locations of the observed cracks, fractures, or corrosion on strap laminates; and removal of the hub assembly from service. This amendment is needed to clarify the strap pack rejection criteria and simplify the recording requirements.

EFFECTIVE DATE: October 27, 1989.

Compliance: As indicated in the body of this amended AD.

ADDRESSES: The applicable service information notices may be obtained from MDHC Technical Publications, Building 543/D214, McDonnell Douglas Helicopter Company, 5000 E. McDowell Road, Mesa, Arizona 85205-9797; telephone (602) 891-6484, or may be examined in the Office of the Assistant Chief Counsel, FAA, Southwest Region, Room 158, Building 3B, 4400 Blue Mound Road, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Mr. Sol Davis, Aerospace Engineer, Airframe Branch, ANM-123L, Northwest Mountain Region, Los Angeles Aircraft Certification Office, 3229 E. Spring Street, Long Beach, California 90806-2425, telephone (213) 988-5233.

SUPPLEMENTARY INFORMATION: This amendment amends Amendment 39-6051 (54 FR 105; January 4, 1989), AD 89-02-01, which currently requires repetitive inspections of main rotor blade retention strap (strap pack) laminates for cracks and failures; recording of the locations of the observed cracks, fractures, or corrosion on strap laminates; and removal of a hub assembly from service in accordance with more stringent rejection criteria on MDHC Model 369D, E, F, and FF helicopters. After issuing Amendment 39-6051, the FAA received a report that there is confusion in meeting the recording requirements of paragraph (g). In addition, the strap pack rejection criteria, as referred to in both paragraphs (f) and (g), can be simplified. Therefore, the FAA is amending Amendment 39-6051 by revising paragraph (f) to state only the strap pack rejection criteria and by revising paragraph (g) to include only reecording directions.

Since this amendment provides a clarification only, and imposes no additional burden on any person, notice and public procedure hereon are unnecessary, and the amendment may be made effective in less than 30 days.

The regulations adopted herein will not have substantial direct effects on the States, or 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.

The FAA has determined that this regulation is clarifying in nature and imposes no further cost. Therefore, I certify that this action: (1) is not a "major rule" under Executive Order 12291; and (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the final evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Regional Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportaiton, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

PART 39—AIRWORTHINESS DIRECTIVES

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of part 39 of the Federal Aviation Regulations as follows:

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by amending Amendment 39-6051 (54 FR 105; January 4, 1989), AD 89-02-01, by revising paragraphs (f) and (g) to read as follows:

McDonnell Douglas Helicopter Company (Hughes Helicopter, Inc.): Applies to Model 369D, E, F, and FF helicopters, certificated in any category, with main rotor hub retention straps having part number (P/N) 369D21210-BSC or -501 installed. (Docket No. 88-ASW-43)

Compliance is required as indicated, unless already accomplished.

* * * * *

(f) Replace the hub assembly, P/N 369D21200, with a serviceable assembly prior to further flight if, as a result of the inspection required by paragraph (a), (b), (c), (d), or (e) above, a strap pack, P/N 369D21210–BSC or –501, is rejected (using the rejection criteria in the applicable SIN under CAUTION following paragraph e of Part I—Inspection Procedures).

g. For strap packs which contain observed damage but are not rejected by the criteria of paragraph (f)—

(1) Record in the maintenance record (Ref. § 43.9) the locations of observed cracks, fractures, or corrosion in each strap laminate in a manner which includes—

(i) Blade color;

(ii) Strap part numbers and serial number;

(iii) Laminate number (top being number one);

(iv) Leg location (lead or lag); and

(v) Tongue location (The tongue location is not the same as the outboard end).

Note: Strap packs containing cracks in outboard end locations are rejected by the criteria of paragraph (f).

(2) Record for each strap pack—

(i) The number of laminate failures;

(ii) The number of laminates cracked in the same leg; and

(iii) The number of gaps.

* * * * *

This amendment becomes effective October 27, 1989.

This amendment amends Amendment 39–6051 (54 FR 105; January 4, 1989). AD 89–02–01.

Issued in Fort Worth, Texas on September 19, 1989.

James D. Erickson,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 89–23136 Filed 9–29–89; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 87F–0330]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amended the food additive regulations to provide for the safe use of 3a,4,7,7a-tetrahydromethyl-4,7-methanoisobenzofuran-1,3-dione grafted onto ethylene polymers, intended to contact food. This action is in response to a petition filed by Keller and Heckman.

DATES: Effective October 2, 1989; written objections and requests for a hearing by November 1, 1989.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of November 2, 1987 (52 FR 42043), FDA announced that a food additive petition (FAP 7B4043) had been filed by Keller and Heckman, 1150 17th St. NW., Washington, DC 20036, proposing that § 177.1520 *Olefin polymers* (21 CFR 177.1520) be amended to provide for the safe use of 3a,4,7,7a-tetrahydromethyl-4,7-methanoisobenzofuran-1,3-dione for grafting onto ethylene polymers complying with 21 CFR 177.1520(c), item 2.2, intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe for food-contact use. Therefore, the agency is amending § 177.1520 by adding a new copolymer in paragraph (a)(5) and adding a new entry in the table in paragraph (c) to provide for the safe use of 3a,4,7,7a-tetrahydromethyl-4,7-methanoisobenzofuran-1, 3-dione grafted onto ethylene polymers intended to contact food. Under § 177.1520(a)(5), the ethylene polymers must comply with item 2.2 of § 177.1520(c).

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before November 1, 1989, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to the presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 177.1520 is amended by adding new paragraph (a)(5) and by adding a new entry 5 in the table in paragraph (c) to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(a) * * *

(5) Polyethylene graft copolymers consist of polyethylene complying with item 2.2 of paragraph (c) of this section which subsequently has 3a,4,7,7a-tetrahydromethyl-4,7-methanoisobenzofuran-1,3-dione grafted

onto it at a level not to exceed 1.7 percent by weight of the finished copolymer.

* * * * *

Olefin polymers	Density	Melting point (MP) or softening point (SP) (Degrees Centigrade)	Maximum extractable fraction (expressed as percent by weight of polymer) in N-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
(c) Specifications:				
*	*	*	*	*
5. Polyethylene copolymer described in paragraph (a)(5) of this section and having a melt index not to exceed 2, for use, either alone or in blends with other olefin polymers, subject to the limitation that when contacting foods of types III, IV-A, V, VI-C, VII-A, VIII, and IX identified in § 176.170(c) of this chapter, Table 1, the thickness of the film (in mils) containing the polyethylene graft copolymer times the concentration of the polyethylene graft copolymer shall not exceed a value of 2.	Not less than 0.94		0.45 pct at 15 °C	1.8 pct at 25 °C.

* * * * *

Dated: September 15, 1989.

Fred R. Shank,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-23138 Filed 9-29-89; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 455

[Docket No. 89N-0325]

Antibiotic Drugs; Aztreonam Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug regulations to provide for the inclusion of accepted standards for a new dosage form of aztreonam, aztreonam injection. The manufacturer has supplied sufficient data and information to establish its safety and efficacy.

DATES: Effective November 1, 1989; written comments, notices of participation, and request for hearing by November 1, 1989; data, information, and analyses to justify a hearing by December 1, 1989.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Peter A. Dionne, Center for Drug Evaluation and Research (HFD-520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: FDA has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to a request for approval of a new dosage form of aztreonam, aztreonam injection. The agency has concluded that the data supplied by the manufacturer concerning this antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended in part 455 (21 CFR part 455) by adding new § 455.4, redesignating § 455.204 as § 455.204a, and adding new §§ 455.204 and 455.204b to provide for the inclusion of accepted standards for this product.

Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Submitting Comments and Filing Objections

This final rule announces standards that FDA has accepted in a request for approval of an antibiotic drug. Because this final rule is not controversial and because when effective it provides notice of accepted standards, FDA finds that notice and comment procedure is unnecessary and not in the public interest. This final rule, therefore, is effective November 1, 1989. However, interested persons may, on or before November 1, 1989, submit comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this final rule may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before November 1, 1989, a written notice of participation and request for hearing, and (2) on or before December 1, 1989, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 314.300. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment