

further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared 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 98-06-32 EUROCOPTER FRANCE:

Amendment 39-10411. Docket No. 97-SW-34-AD.

Applicability: Model AS 332C, L, and L1 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 (b) 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 failure of a main rotor blade horn eye bolt (eye bolt) bearing due to premature wear caused by an improper axial pre-load, which could result in loss of main rotor blade pitch control and subsequent loss

of control of the helicopter, accomplish the following:

(a) Within 50 hours time-in-service (TIS) after the effective date of this AD for any eye bolt currently installed, or prior to installing any replacement eye bolt, that has less than 500 hours TIS, grease and inspect the eye bolt assembly in accordance with paragraphs CC.1 through CC.3 of Eurocopter France Telex Service 39/0206/1997, dated July 25, 1997, (containing Eurocopter France AS 332 Telex Service No. 01.00.52 R1). If the expelled grease has a "blackish" color or contains metal particles, or if the rotational torque on the eye bolt exceeds 30,000 millimeter grams (2.655 inch-lbs.), replace the eye bolt bearings with airworthy eye bolt bearings in accordance with paragraph CC.4B of the Telex Service.

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

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Rotorcraft Standards Staff.

(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 helicopter to a location where the requirements of this AD can be accomplished.

(d) The actions shall be done in accordance with Eurocopter France Telex Service 39/0206/1997, dated July 25, 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 American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053-4005, telephone (972) 641-3460, fax (972) 641-3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on April 2, 1998.

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) Telegraphic AD 97-174-063(AB), dated August 1, 1997.

Issued in Fort Worth, Texas, on March 11, 1998.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98-6966 Filed 3-17-98; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 29165; Amdt. No. 408]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

EFFECTIVE DATE: 0901 UTC, April 23, 1998.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS-420), Technical Programs Division, Flight Standards Service Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its

timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days. The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current.

It, therefore—(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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 95

Airspace, Navigation (air).

Issued in Washington, D.C. on March 13, 1998.

Tom E. Stuckey,

Acting Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the

Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC.

PART 95—[AMENDED]

1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44719, 44721.

2. Part 95 is amended to read as follows:

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES & CHANGEOVER POINTS

[Amendment 408 effective date, April 23, 1998]

From	To	MEA
§ 95.6009 VOR Federal Airway 9 is Amended to Read in Part		
Madison, WI VORTAC	Oshkosh, WI VORTAC	3000
§ 95.6013 VOR Federal Airway 13 is Amended to Read in Part		
Rich Mountain, OK VORTAC	*Hades, AR FIX	**4600
*5000—MRA		
**3900—MOCA		
Fort Smith, AR VORTAC	*Cheso, AR FIX	**3400
*5000—MRA		
**2700—MOCA		
Cheso, AR FIX	Barkk, AR FIX	3500
Barkk, AR FIX	Razorback, AR VORTAC	3500
§ 95.6069 VOR Federal Airway 69 is Amended to Read in Part		
Pine Bluff, AR VOR/DME	Billi, AR FIX	2000
§ 95.6076 VOR Federal Airway 76 is Amended to Read in Part		
Welch, TX FIX	Patts, TX FIX	*6100
*5200—MOCA		
§ 95.6081 VOR Federal Airway 81 is Amended to Read in Part		
Patts, TX FIX	*Welch, TX FIX	**6100
*7000—MRA		
**5200—MOCA		
§ 95.6107 VOR Federal Airway 107 is Amended to Read in Part		
Fillmore, CA VORTAC	Pirue, CA FIX	*8000
	SE BND	*9000
	NW BND	
*7200—MOCA		
Pirue, CA FIX	Reyes, CA FIX	*11000
*9200—MOCA		
Derbb, CA FIX	Avenal, CA VORTAC	*7000
*6500—MOCA		
§ 95.6120 VOR Federal Airway 120 is Amended to Read in Part		
Fryre, SD FIX	Sioux Falls, SD VORTAC	3700

REVISIONS TO MINIMUM ENROUTE IFR ALTITUDES & CHANGEOVER POINTS—Continued
 [Amendment 408 effective date, April 23, 1998]

From	To	MEA	
§ 95.6124 VOR Federal Airway 124 is Amended to Read in Part			
Bonham, TX VORTAC	Paris, TX VOR/DME	2400	
Deens, AR FIX	Hot Springs, AR VOR/DME	*5000	
*2600—MOCA			
Lonns, AR FIX	Little Rock, AR VORTAC	2300	
Little Rock, AR VORTAC	Tafte, AR FIX	*4000	
*1600—MOCA			
Tafte, AR FIX	*Hille, AR FIX	**6000	
*6000—MRA			
**1500—MOCA			
§ 95.6278 VOR Federal Airway 278 is Amended to Read in Part			
Guthrie, TX VORTAC	Nifde, TX FIX	*4500	
*3000—MOCA			
Nifde, TX FIX	Poste, TX FIX	*3300	
*2600—MOCA			
Poste, TX FIX	Bowie, TX VORTAC	*3300	
*2500—MOCA			
Bonham, TX VORTAC	Paris, TX VOR/DME	2400	
Texarkana, AR VORTAC	Warlo, AR FIX	2200	
Warlo, AR FIX	Locus, AR FIX	*3000	
*1700—MOCA			
Locus, AR FIX	Monticello, AR VOR/DME	*2500	
*1600—MOCA			
Monticello, AR VOR/DME	Greenville, MS VOR/DME	*2000	
*1500—MOCA			
§ 95.6319 VOR Federal Airway 319 is Amended to Read in Part			
Eyaks, AR FIX	Johnstone Point, AK VORTAC	5000	
§ 95.6341 VOR Federal Airway 341 is Amended to Read in Part			
Madison, WI VORTAC	Oshkosh, WI VORTAC	3000	
§ 95.6369 VOR Federal Airway 369 is Amended to Read in Part			
Navasota, TX VORTAC	Bilee, TX FIX	*2300	
*1800—MOCA	MAA—17500		
Bilee, TX FIX	Groesbeck, TX VOR/DME	*2300	
*1800—MOCA	MAA—17500		
Groesbeck, TX VOR/DME	Dallas/Fort Worth, TX VORTAC	3400	
	MAA—17500		
§ 95.6480 VOR Federal Airway 480 is Amended to Read in Part			
Kipnuk, AK VOR/DME	Bethel, AK VORTAC	2000	
§ 95.6532 VOR Federal Airway 532 is Amended to Read in Part			
Fort Smith, AR VORTAC	*Akins, OK FIX	2500	
*3000—MRA			
Akins, OK FIX	Okmulgee, OK VOR/DME	*3000	
*2200—MOCA			
§ 95.6573 VOR Federal Airway 573 is Amended to Read in Part			
Texarkana, AR VORTAC	Pikes, AR FIX	*3500	
*1800—MOCA			
Pikes, AR FIX	Marki, AR FIX	*3500	
*2100—MOCA			
Lonns, AR FIX	Little Rock, AR VORTAC	2300	
From	To	MEA	MAA
§ 95.7104 Jet Route No. 104 is Amended to Read in Part			
San Simon, AZ VORTAC	Socorro, NM VORTAC	20000	45000

From	To	Changeover points	
		Distance	From
§ 95.8003 VOR Federal Airway Changeover Points Airway Segment V-16 is Amended to Read in Part			
Texarkana, AR VORTAC	Pine Bluff, AR VOR/DME	62	Texarkana
V-124 is Amended to Delete			
Hot Springs, AR VOR/DME			

[FR Doc. 98-7027 Filed 3-17-98; 8:45 am]
 BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Amoxicillin Trihydrate and Clavulanate Potassium

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 two supplemental new animal drug applications (NADA's) filed by Pfizer, Inc. The supplemental NADA's provide for oral use amoxicillin trihydrate and clavulanate potassium tablets and suspension for treatment of dogs for periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.

EFFECTIVE DATE: March 18, 1998.
FOR FURTHER INFORMATION CONTACT: Mary E. Reese, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20857, 301-594-1617.
SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA's 55-099 and 55-101 that provide for oral use of amoxicillin trihydrate and clavulanate potassium tablets and suspension for treatment of dogs for periodontal infections due to susceptible strains of aerobic and anaerobic bacteria. The products are limited to use by or on the order of a licensed veterinarian. The supplemental NADA's are approved as of December 23, 1997, and the regulations are amended in 21 CFR 520.88g and 520.88h to reflect the approval. The basis for approval is discussed in the freedom of information summary.
 In accordance with the freedom of information provisions of 21 CFR part

20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of the supplemental applications may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these approvals for nonfood-producing animals qualify for 3 years of marketing exclusivity beginning December 23, 1997, because the supplemental applications contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for approval of the applications and conducted or sponsored by the applicant. Three years of marketing exclusivity applies only to use of Clavamox® tablets and suspension in dogs for treatment of periodontal infections caused by susceptible strains of aerobic and anaerobic bacteria.

FDA has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.
 Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.88g is amended in paragraph (c)(1)(ii) by adding a new sentence at the end of the paragraph to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium film-coated tablets.

* * * * *
 (c) * * *
 (1) * * *
 (ii) * * * Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.
 * * * * *

3. Section 520.88h is amended in paragraph (c)(1)(ii) by adding a new sentence at the end of the paragraph to read as follows:

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

* * * * *
 (c) * * *
 (1) * * *
 (ii) * * * Treatment of periodontal infections due to susceptible strains of aerobic and anaerobic bacteria.
 * * * * *

Dated: February 27, 1998.

Stephen F. Sundlof,
 Director, Center for Veterinary Medicine.
 [FR Doc. 98-6907 Filed 3-17-98; 8:45 am]
 BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Desoxycorticosterone Pivalate

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 new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for use of desoxycorticosterone pivalate as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.
EFFECTIVE DATE: March 18, 1998.