the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Note 3: The subject of this AD is addressed in Dutch airworthiness directive 1999–093, dated June 30, 1999.

Effective Date

(e) This amendment becomes effective on June 9, 2004.

Issued in Renton, Washington, on April 22, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–10138 Filed 5–4–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 30412; Amdt. No. 448]

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, June 10, 2004.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

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.

Conclusion

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, DC on April 30, 2004.

James J. Ballough,

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, June 10, 2004.

■ 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 IFR ALTITUDES & CHANGEOVER POINTS

[Amendment 448—Final Effective Date June 10, 2004]

From	To	MEA
§ 95.6001 Victor Routes—U.S.		
§ 95.6003 VOR Federal Airway 3 Is Amended To Read in Part		
Savannah, GA VORTAC	Owens, SC FIX	*3,000
*1,500–MOCA		
Owens, SC FIX	Vance, SC VORTAC	2,000
§ 95.6016 VOR Federal Airway 16 is Amended To Read in Part		
Damas, TN FIX	*Stove, VA FIX	7,500
*7,500–MCA Stove FIX SW BND		
Stove, VA FIX	Speel, VA FIX	6,000
Speel, VA FIX	Pulaski, VA VORTAC	5,400

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS—Continued

[Amendment 448—Final Effective Date June 10, 2004]

From	To	MEA
§ 95.059 VOR Federal Airway 58 Is Amended To Read in Part		
Grace, PA FIX	*Eared, PA FIX	3,400
*3,400–MRA		
§ 95.6136 VOR Federal Airway 136 Is Amended To Read in Part		
Damas, TN FIX	*Stove, VA FIX	7,500
*7,500–MCA Stove FIX SW BND		
Stove, VA FIX	Speel, VA FIX	6,000
Speel, VA FIX	Pulaski, VA VORTAC	5,400
§ 95.6226 VOR Federal Airway 226 Is Amended To Read in Part		
Grace, PA FIX	*Earned, PA FIX	3,400
*4,000–MRA		
Earned, PA FIX	Clarion, PA VOR/DME	3,400
§ 95.6330 VOR Federal Airway 330 Is Amended To Read in Part		
Osity, ID FIX	*Jackson, WY VOR/DME	14,000
*13,200–MCA Jackson VOR/DME		
§ 95.6465 VOR Federal Airway 465 Is Amended To Read in Part		
Malad City, ID VOR/DME	Lundi, ID FIX	.....
	SW BND	11,400
	NE BND	14,000
Lundi, ID FIX	Jackson, WY VOR/DME	*15,000
*13,100–MOCA		
§ 95.6520 VOR Federal Airway 520 Is Amended To Read in Part		
Dubois, ID VORTAC	*Jackson, WY VOR/DEM	15,000
*14,600–MCA Jackson VOR/DME		

From	To	Changeover Points	
		Distance	From
§ 95.8003 VOR Federal Airway Changeover Points			
V–16 Is Amended To Delete Changeover Point			
Holston Mountain, TN VORTAC	Pulaski, VA VORTAC	69	Holston Mountain
V–136 Is Amended To Delete Changeover Point			
Holston Mountain, TN VORTAC	Pulaski, VA VORTAC	69	Holston Mountain
V–328 Is Amended To Delete Changeover Point			
Big Piney, WY VOR/DME	Jackson, WY VOR/DM	51	Big Piney
V–330 Is Amended To Delete Changeover Point			
Idaho Falls, ID VOR/DME	Jackson, WY VOR/DME	48	Idaho Falls
V–465 Is Amended To Add Changeover Point			
Malad City, ID VOR/DME	Jackson, WY VOR/DME	60	Malad City
V–520 Is Amended To Delete Changeover Point			
Dubois, ID VORTAC	Jackson, WY VOR/DME	60	Dubois

[FR Doc. 04–10237 Filed 5–4–04; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 an abbreviated new animal drug application (ANADA) filed by Veterinary Laboratories, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous parasites.

DATES: This rule is effective May 5, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, filed ANADA 200–341 that provides for oral use of SPARMECTIN–E (ivermectin) Liquid for Horses for the treatment and control of various species of internal and cutaneous parasites. Veterinary Laboratories' SPARMECTIN–E Liquid for Horses is approved as a generic copy of Merial Ltd.'s EQVALAN (ivermectin) Oral Liquid for Horses, approved under NADA 140–439. The ANADA is approved as of March 8, 2004, and the regulations are amended in 21 CFR 520.1195 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject 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.

§ 520.1195 [Amended]

■ 2. Section 520.1195 is amended in paragraph (b)(1) by adding ''000857'' in numerical sequence.

Dated: April 23, 2004.

Catherine P. Beck,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–10193 Filed 5–4–04; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin Gel

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 supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for oral use of moxidectin gel in horses and ponies for the treatment and control of an additional species of small strongyle.

DATES: This rule is effective May 5, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141–087 for QUEST (moxidectin 2.0%) Gel, used for the treatment and control of various species of internal parasites in horses and ponies. The supplemental NADA provides for the addition of one new species of adult small strongyle and for the speciation of adult small strongyles in product labeling. The supplemental NADA is approved as of March 17, 2004, and 21 CFR 520.1452 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 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)), this approval qualifies for 3 years of marketing exclusivity beginning March 17, 2004. Exclusivity applies only to the new effectiveness claim for adult *Coronocyclus labratus* for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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: