the availability of this material at NARA, call 202–741–6030, or go to: http://

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

Effective Date
(e) This amendment becomes effective on

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]

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,
sure 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:

REVIZIONS TO IFR ALTITUDES & CHANGEOVER POINTS

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

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§95.6001 Victor Routes—U.S.

§95.6003 VOR Federal Airway 3 Is Amended To Read in Part

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§95.6016 VOR Federal Airway 16 is Amended To Read in Part

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REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS—Continued

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

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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.

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 delegated 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:


§ 520.1195 [Amended]

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


Catherine P. Beck,
Acting Director, Center for Veterinary Medicine.

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.

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 specification 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 Coronoclycus labratus for which new data were required.

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 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 delegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

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.