

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Susanville, CA [NEW]

Susanville Municipal Airport, CA
(Lat. 40°22'37" N, long. 120°34'23" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Susanville Municipal Airport and within 2 miles each side of the 134° bearing from the Susanville Municipal Airport extending from the 6.5-mile radius to 10.3 miles southeast of the Susanville Municipal Airport and within 2 miles each side of the 339° bearing from the Susanville Municipal Airport extending from the 6.5-mile radius to 10 miles northwest of the Susanville Municipal Airport.

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Issued in Los Angeles, California, on July 8, 2003.

Stephen J. Lloyd,

*Acting Manager, Air Traffic Division,
Western-Pacific Region.*

[FR Doc. 03–18518 Filed 7–21–03; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2003–15256; Airspace
Docket No. 03–ACE–49]

Modification of Class E Airspace; Falls City, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This document confirms the effective date of the direct final rule which revises Class E airspace at Falls City, NE.

EFFECTIVE DATE: 0901 UTC, September 4, 2003.

FOR FURTHER INFORMATION CONTACT:

Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on May 30, 2003 (68 FR 32357). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on September 4, 2003. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

Issued in Kansas City, MO on July 11, 2003.

Herman J. Lyons, Jr.

Manager, Air Traffic Division Central Region.

[FR Doc. 03–18514 Filed 7–21–03; 8:45 am]

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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 Paste; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Merial, Ltd. The supplemental NADA provides for the addition of several new species of internal parasites to product labeling for ivermectin paste for horses. This action is being taken to ensure

accuracy and clarity in the agency's regulations.

DATES: This rule is effective July 22, 2003.

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: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed a supplement to NADA 134–314 for EQVALAN (ivermectin) Paste for Horses. The supplemental application provides for the use of ivermectin paste for the treatment and control of *Craterostomum acuticaudatum*, *Petrovinema poculatum*, and *Coronocylcus* spp., including: *C. coronatus*, and *C. labratus*. Also, the label descriptions of some currently-approved parasite genera are being revised to add included species for which data already exists in the NADA file and to reflect changes in scientific nomenclature. The supplemental NADA is approved as of April 2, 2003, and 21 CFR 520.1192 is amended 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 part 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 Dockets Management Branch (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 supplemental approval qualifies for 3 years of marketing exclusivity beginning April 2, 2003. This marketing exclusivity only applies to the parasites 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:

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 520.1192 is amended by revising paragraphs (a) and (b); by redesignating paragraph (d) as paragraph (e); by adding new paragraph (d); by removing the last sentence of newly redesignated paragraphs (e)(1)(iii) and (e)(2)(iii); by redesignating new paragraph (e)(1)(ii) as paragraph (e)(1)(ii)(B); in newly redesignated paragraph (e)(1)(ii)(B) by removing “spp.” after “*Onchocerca*” and by adding in its place “sp.”; and by adding new paragraph (e)(1)(ii)(A) to read as follows:

§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.0187 mg (1.87 percent) or 0.00153 mg (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) No. 050604 for use of a 1.87-percent paste as in (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section and a 0.153-percent paste for use as in paragraph (e)(2) of this section.

(2) Nos. 051311 and 059130 for use of a 1.87-percent paste for use as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

* * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use—(1) Horses—(i) Amount.* 200 micrograms per kilogram (91 micrograms per pound) of body weight.

(ii) *Indications for use—(A)* For treatment and control of large strongyles (adults) (*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*; *Triodontophorus* spp., including *T. brevicauda* and *T. serratus*; and *Craterostomum acuticaudatum*); small strongyles including those resistant to some benzimidazole class compounds (adults and fourth-stage larvae) (*Coronocylus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*;

Cylicocylus spp., including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*; *Cylicodontophorus* spp.; *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; and *Petrovinema poculatum*); pinworms (adults and fourth-stage larvae) (*Oxyuris equi*); ascarids (adults and third- and fourth-stage larvae) (*Parascaris equorum*); hairworms (adults) (*Trichostrongylus axei*); large-mouth stomach worms (adults) (*Habronema muscae*); bots (oral and gastric stages) (*Gasterophilus* spp., including *G. intestinalis* and *G. nasalis*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

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Dated: July 8, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 03-18163 Filed 7-21-03; 8:45 am]

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DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau****27 CFR Parts 40 and 275**

[T.D. TTB-4; ATF Notice No. 962]

RIN 1513-AA18

Elimination of Statistical Classes for Large Cigars (2000R-410P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Final rule (Treasury Decision).

SUMMARY: This final rule removes the eight statistical classes for large cigars prescribed in TTB regulations. Since tobacco manufacturers and importers no longer use these statistical classes to report removals of large cigars subject to tax, this final rule eliminates obsolete regulations.

DATES: The effective date of this final rule is August 21, 2003.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, 650 Massachusetts Avenue NW., Washington, DC 20226 (telephone: 202-927-8210 or e-mail: ttbquestions@ttb.gov).

SUPPLEMENTARY INFORMATION:

ATF-TTB Transition

Effective January 24, 2003, the Homeland Security Act of 2002 divided the Bureau of Alcohol, Tobacco and Firearms (ATF) into two new agencies, the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the Department of the Treasury and the Bureau of Alcohol, Tobacco, Firearms, and Explosives in the Department of Justice. The taxation of tobacco products remains a Department of the Treasury function and is the responsibility of TTB. References to the former ATF and the new TTB in this document reflect the time frame, before or after January 24, 2003.

Final Rule Background

On November 5, 2002, ATF published a notice of proposed rulemaking in the **Federal Register** (ATF Notice No. 962, 67 FR 67340) to solicit comments about the elimination of obsolete tobacco regulations in 27 CFR parts 40 and 275. These regulations prescribed eight statistical classes for large cigars subject to tax. The first seven classes (Classes A through G) covered large cigars selling for \$235.294 or less per thousand, while the eighth class (Class H) covered those selling for more than \$235.294 per thousand.

Since January 1, 2001, manufacturers of tobacco products report information about large cigars subject to tax in two statistical classes. Tobacco importers also no longer use these eight statistical classes. The reduction in the number of statistical classes reduces industry's reporting burden, but does not jeopardize our ability to protect the revenue or adversely affect our compilation of tobacco statistics for use by governments and the public.

We did not receive any comments on ATF Notice No. 962. For these reasons and those discussed in the notice, we are issuing this final rule.

Regulatory Requirements**Regulatory Flexibility Act**

We certify that this final rule will not have a significant economic impact on a substantial number of small entities. Consequently, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. In accordance with 26 U.S.C. 7805(f), we sent the notice of proposed rulemaking to the Chief Counsel for Advocacy of the Small Business Administration.

Executive Order 12866

We have determined that this rule is not a significant regulatory action as defined by Executive Order 12866.