

**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.

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(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.*

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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](mailto: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.