§ 520.1193 Ivermectin tablets and chewables.

(a) Specifications. (1) Each tablet or chewable contains 68, 136, or 272 micrograms (mcg) ivermectin.

(2) Each chewable contains 55 or 165 mcg ivermectin.

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

(1) No. 050604 for use of tablets or chewables described in paragraph (a)(1) as in paragraph (d)(1) and chewables described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(2) No. 065274 for use of tablets described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) Conditions of use—(1) Dogs. For use in dogs 6 weeks of age and older as follows:

(i) Amount. 6.0 mcg per kilogram (kg) of body weight (2.72 mcg per pound [lb]), minimum. Up to 25 lb, 68 mcg; 26 to 50 lb, 136 mcg; 51 to 100 lb, 272 mcg; over 100 lb, a combination of the appropriate tablets. Administer at monthly dosing intervals.

(ii) Indications for use. To prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (Dirofilaria immitis) for 1 month (30 days) after infection.

(2) Cats. For use in cats 6 weeks of age and older as follows:

(i) Amount. Up to 2.3 kilograms (up to 5 lb), 55 mcg; 2.3 to 6.8 kilograms (5 to 15 lb), 165 mcg; over 6.8 kilograms (15 lb), a combination of the appropriate chewables (recommended minimum dose of 24 mcg/kg of body weight (10.9 mcg/lb)). Administer once a month.

(ii) Indications for use. To prevent feline heartworm disease by eliminating the tissue stage of heartworm larvae Dirofilaria immitis for a month (30 days) after infection, and for removal and control of adult and immature (L4) hookworms Ancylostoma tubaeforme and A. braziliense.


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the IRC or the FAA Act, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director that were not previously delegated and places those authorities with the “appropriate ATF officer.” All of the authorities of the Director that were not previously delegated are also placed with the “appropriate ATF officer.” Along with this final rule, ATF is publishing ATF Order 1130.12, Delegation of the Director’s Authorities in 27 CFR part 251, Importation of Distilled Spirits, Wines, and Beer, which delegates authorities to appropriate ATF officers. The effect of these changes is to consolidate all delegations of authority in part 251 into one delegation instrument. This action both simplifies the process for determining what ATF officer is authorized to perform a particular function and facilitates the updating of delegations to all other parts of Title 27 of the Code of Federal Regulations through separate rulemakings.

Miscellaneous Changes

Section 136(a) of Public Law 103–465 (108 Stat. 4841), known as the Uruguay Round Agreements Act, repealed section 5001(a)(3) of the Internal Revenue Code of 1986. This section had previously imposed a tax on perfumes imported into the United States containing distilled spirits, a tax of $13.50 per wine gallon. Consequently, we are removing sections in part 251 of the Code of Federal Regulations that refer to this repealed tax.

Corrections

Sections 251.55 and 251.59 are being amended to remove references to obsolete regulations and an obsolete form.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Pub. L. 104–13, 44 U.S.C. chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no new or revised recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply. A copy of this final rule was submitted to the Chief Counsel for Advocacy of the Small Business Administration in accordance with 26 U.S.C. 7805(f). No comments were received.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action because it will not: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) Create a significant inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b). Similarly it is unnecessary to subject this final rule to the effective date limitation of 5 U.S.C. 553(d).

DRAFTING INFORMATION

The principal author of this document is Robert Ruhl. Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

LIST OF SUBJECTS IN 27 CFR PART 251

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Beer, Customs duties and inspection, Electronic funds transfers, Excise taxes, Imports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Spices and flavorings, Transportation, Warehouses, Wine.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows:

PART 251—IMPORTATION OF DISTILLED SPIRITS, WINES, AND BEER

Paragraph 1. The authority citation for part 251 continues to read as follows:


§ 251.2, 251.11, 251.77, 251.181, 251.206, 251.209 and 251.221 [Amended]

Par. 2. Remove the words “Director” each place it appears and add, in substitution, the words “appropriate ATF officer” in the following places:

(a) Section 251.2(a);
(b) The definition of “Liquor bottle” in § 251.11:
(c) Section 251.77(d);
(d) Section 251.181(a);
(e) Section 251.206;
(f) Section 251.209; and
(g) The undesignated paragraph following § 251.221(b)(3).

Par. 3. Amend § 251.2 by adding a sentence at the end of paragraph (a) and revising paragraph (b) to read as follows:
§ 251.2 Forms prescribed.
(a) * * * The form will be filed in accordance with the instructions for the form.
(b) Forms may be requested from the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 4. In Subpart A—Scope of Regulations, a new § 251.3 is added as follows:

§ 251.3 Delegations of the Director.
All of the regulatory authorities of the Director contained in part 251 of the regulations are delegated to appropriate ATF officers. These ATF officers are specified in ATF Order 1130.12. Delegation of the Director’s Authorities in 27 CFR part 251, Importation of Distilled Spirits, Wines, and Beer. ATF delegation orders, such as ATF Order 1130.12, are available to any interested person by mailing a request to the ATF Distribution Center, P.O. Box 5950, Springfield, Virginia 22150–5950, or by accessing the ATF web site (http://www.atf.treas.gov/).

Par. 5. Section 251.11 is further amended by:
(a) Removing the definitions of “ATF Officer”, “Region”, and “Regional Director (compliance)”;
(b) Adding a new definition of “Appropriate ATF officer” to read as follows:

§ 251.11 Meaning of Terms.
* * * * * 
Appropriate ATF officer. An officer or employee of the Bureau of Alcohol, Tobacco and Firearms (ATF) authorized to perform any functions relating to the administration or enforcement of this part by ATF Order 1130.12. Delegation of the Director’s Authorities in 27 CFR Part 251, Importation of Distilled Spirits, Wines, and Beer.
* * * * *

Par. 6. Revise the heading for Subpart D to read as follows: Subpart D—Tax on Imported Distilled Spirits, Wines, and Beer.

Par. 7. Revise the designated center heading following the heading for Subpart D to read as follows: Distilled Spirits.

Par. 8. Remove § 251.41.

Par. 9. Redesignate § 250.40a as § 250.41.

Par. 10. Remove the words and punctuation “Regulations 1,” and “(Form 1631)” in § 251.55.

Par. 11. Remove the words and punctuation “Regulations 4,” each place that they appear in § 251.59.

Par. 12. Amend § 251.77(d) by removing the words “ATF National Laboratory” and adding, in substitution, the words “appropriate ATF officer”.

Par. 13. Revise the second sentence of § 251.136(a) to read as follows:

§ 251.136 Filing.
(a) * * * The appropriate ATF officer may, pursuant to an application, authorize files, or an individual file, to be maintained at another business location under the control of the importer, if the alternative location does not cause undue inconvenience to appropriate ATF officers desiring to examine the files or delay in the timely submission of documents, and are not inconsistent with Customs recordkeeping requirements (See 19 CFR part 163).
* * * * *

Par. 14. Revise § 251.137 to read as follows:

§ 251.137 Retention.
All records required by this part, documents or copies of documents supporting these records, and file copies of reports required by this part, must be retained for not less than three years, and during this period must be available, during business hours, for inspection and copying by appropriate ATF or Customs officers. Furthermore, the appropriate ATF officer may require these records to be kept for an additional period of not more than three years in any case where the appropriate ATF officer determines retention necessary or advisable. Any records, or copies thereof, containing any of the information required by this part to be prepared, wherever kept, must also be made available for inspection and copying.

Par. 15. Amend the last sentence of § 251.172 by removing the words “regional director (compliance) in which the consignee is located” and adding, in substitution, the words “appropriate ATF officer”.

Par. 16. Amend § 251.182 by:
(a) Revising paragraphs (b)(1) and (d) to read as follows:

§ 251.182 Application and permit, Form 5150.33.
* * * * *

(b) Application. (1) A Government agency of the United States must apply for a permit to procure and withdraw spirits free of tax on Form 5150.33. Upon approval by the appropriate ATF officer, Form 5150.33 will be returned to the agency.
* * * * *

(d) Cancellation of permit. All permits on Form 5150.33 and previous editions on Form 1444 remain in force until surrendered or canceled. Upon surrender or cancellation, the Government agency must obtain and destroy all photocopied of the permit furnished to port directors of Customs, and forward the original to the appropriate ATF officer for cancellation.
* * * * *

Par. 17. Amend § 251.204 by:
a. Removing the words “to the Director” from the second sentence of paragraph (a);
b. Removing the word “Director” from the third sentence of paragraph (a) and adding, in substitution, the words “appropriate ATF officer”; and

Par. 18. Amend § 251.208 by removing the words “regional director (compliance) of the region in which the port of entry is situated” and adding, in substitution, the words “appropriate ATF officer”.

Par. 19. Revise the introductory text of paragraphs (a) and (b) of § 251.221 to read as follows:

§ 251.221 Alternate methods or procedures.
(a) Application. An importer who desires to use an alternate method or procedure in lieu of a method or procedure prescribed by this part must file an application, in triplicate, with the appropriate ATF officer. Each application must: * * * *

(b) Approval. When an application for use of an alternate method or procedure is received, the appropriate ATF officer must determine whether approval thereof would unduly hinder the effective administration of this part or would result in jeopardy to the revenue. The appropriate ATF officer may approve the alternate method or procedure if such officer finds that: * * * *

Bradley A. Buckles,
Director.
Approved: January 31, 2002.
Timothy E. Skud,
Acting Deputy Assistant Secretary, (Regulatory, Tariff and Trade Enforcement).