

Administration, 7500 Standish Pl.,
Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Blue Ridge Pharmaceuticals, Inc., 4249-105 Piedmont Pkwy., Greensboro, NC 27410, filed ANADA 200-270 that provides for veterinary prescription use of IVERHART (ivermectin) Tablets for prevention of canine heartworm disease by elimination of the tissue stage of heartworm (*Dirofilaria immitis*) larvae for a month after infection. Blue Ridge's IVERHART Tablets is approved as a generic copy of Merial Ltd.'s HEARTGARD Tablets, approved under NADA 138-412. ANADA 200-270 is approved as of November 30, 2001, and 21 CFR 520.1193 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 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.

FDA 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 520.1193 is revised to read as follows:

§ 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*.

Dated: January 31, 2002.

Stephen F. Sundlof,

Center for Veterinary Medicine.

[FR Doc. 02-5060 Filed 3-12-02; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 251

[T.D. ATF-474]

RIN 1512-AC58

Delegation of Authority

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places ATF authorities with the "appropriate ATF officer" and requires that persons file documents required with the "appropriate ATF officer" or in accordance with the instructions on the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word "region." Concurrently with this Treasury Decision, ATF Order 1130.12 is being issued and will be available to the public as specified in this rule. Through this order, the Director has delegated all of the authorities to the appropriate ATF officers and specified the ATF officers with whom applications, notices and other reports, which are not ATF forms, are to be filed. In addition, this final rule removes the regulations relating to a repealed tax on imported perfumes.

EFFECTIVE DATE: This rule is effective March 13, 2002.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Room 5003, Washington, DC 20226 (telephone 202-927-8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120-01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC) and the Federal Alcohol Administration (FAA) Act. The Director has subsequently redelegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain what particular officer is authorized to perform a particular function under chapter 51 of

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 in part 251 that were 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 in the future. As a result, delegations of authority will be reflected in a more timely and user-friendly manner.

In addition, this final rule also eliminates all references in the regulations that identify the ATF officer with whom an ATF form is filed. This is because ATF forms indicate the officer with whom they must be filed. Similarly, this final rule also amends part 251 to provide that the submission of documents other than ATF forms (such as letterhead applications, notices and reports) must be filed with the "appropriate ATF officer" identified in ATF Order 1130.12. These changes will facilitate the identification of the officer with whom forms and other required submissions are to be filed.

This final rule also makes various technical amendments to Subpart A—Scope of Regulations of 27 CFR part 251. First, a new § 251.3 is added to recognize the authority of the Director to delegate regulatory authorities in part 251 and to identify ATF Order 1130.12 as the instrument reflecting such delegations. Second, § 251.2 is amended

to provide that the instructions for an ATF form identify the ATF officer with whom it must be filed.

ATF has made or will make similar changes in 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 serious 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 Ruhf, 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:

Authority: 5 U.S.C. 552(a), 19 U.S.C. 81c, 1202; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5054, 5061, 5111, 5112, 5114, 5121, 5122, 5124, 5201, 5205, 5207, 5232, 5273, 5301, 5313, 5555, 6302, 7805.

§§ 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.

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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 undesignated 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 photocopies of the permit furnished to port directors of Customs, and forward the original to the appropriate ATF officer for cancellation.

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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

c. Removing the word “Director” from the introductory text of paragraph (b) and adding, in substitution the words “appropriate ATF officer”; and

d. Removing the word “Director” from the second sentence of undesignated text following paragraph (b) and adding, in substitution, the words “appropriate ATF officer”.

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:

* * * * *

Signed: January 16, 2002.

Bradley A. Buckles,
Director.

Approved: January 31, 2002.

Timothy E. Skud,
Acting Deputy Assistant Secretary,
(Regulatory, Tariff and Trade Enforcement).
[FR Doc. 02–5880 Filed 3–12–02; 8:45 am]

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