

List of Subjects in 15 CFR Part 705

Administrative practice and procedure, Business and industry, Classified information, Confidential business information, Imports, Investigations, National Security.

For the reasons set forth in the preamble, part 705 of Subchapter A, National Security Industrial Base Regulations is amended as follows:

PART 705—[AMENDED]

1. The authority citation for 15 CFR part 705 is revised to read as follows:

Authority: Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979).

2. Section 705.3 is amended by designating the existing text as paragraph (a) and by adding a new paragraph (b), as follows:

§ 705.3 Commencing an investigation.

(a) * * *

(b) The Secretary shall immediately provide notice to the Secretary of Defense of any investigation initiated under this part.

§ 705.5 [Amended]

3. In § 705.5(a), the reference to "Office of Industrial Resource Administration" is revised to read "Office of Strategic Industries and Economic Security."

4. Section 705.7 is amended by revising paragraph (d) to read as follows:

§ 705.7 Conduct of an investigation.

* * * * *

(d) The Department shall, as part of an investigation, seek information and advice from, and consult with, appropriate officers of the United States or their designees, as shall be determined. The Department shall also consult with the Secretary of Defense regarding the methodological and policy questions raised in the investigation. Upon the request of the Secretary, the Secretary of Defense shall provide the Secretary with an assessment of the defense requirements of the article in question. Communications received from agencies of the U.S. government or foreign governments will not be made available for public inspection.

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§§ 705.7 and 705.8 [Amended]

5. In §§ 705.7(b) and 705.8(b)(6), the references to room number "H-4886" are revised to read "H-4525".

6. Section 705.10 is revised to read as follows:

§ 705.10 Report of an investigation and recommendation.

(a) When an investigation conducted pursuant to this part is completed, a report of the investigation shall be promptly prepared.

(b) The Secretary shall report to the President the findings of the investigation and a recommendation for action or inaction within 270 days after beginning an investigation under this part.

(c) An Executive Summary of the Secretary's report to the President of an investigation, excluding any classified or proprietary information, shall be published in the **Federal Register**. Copies of the full report, excluding any classified or proprietary information, will be available for public inspection and copying in the Bureau of Export Administration Freedom of Information Records Inspection Facility, Room H-4525, U.S. Department of Commerce, 14th Street, N.W., Washington, D.C. 20230; tel. (202) 482-5653.

7. A new section 705.11 is added to read as follows:

§ 705.11 Determination by the President and adjustment of imports.

(a) Upon the submission of a report to the President by the Secretary under § 705.10(b) of this part, in which the Department has found that an article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, the President is required by Section 232(c) of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862(c)) to take the following action

(1) Within 90 days after receiving the report from the Secretary, the President shall determine:

(i) Whether the President concurs with the Department's finding; and

(ii) If the President concurs, the nature and duration of the action that must be taken to adjust the imports of the article and its derivatives so that the such imports will not threaten to impair the national security.

(2) If the President determines to take action under this section, such action must be taken no later than fifteen (15) days after making the determination.

(3) By no later than thirty (30) days after making the determinations under paragraph (a)(1) of this section, the President shall submit to the Congress a written statement of the reasons why the President has decided to take action, or refused to take action.

(b) If the action taken by the President under this section is the negotiation of an agreement to limit or restrict the importation into the United States of the

article in question, and either no such agreement is entered into within 180 days after making the determination to take action, or an executed agreement is not being carried out or is ineffective in eliminating the threat to the national security, the President shall either:

(1) Take such other action as deemed necessary to adjust the imports of the article so that such imports will not threaten to impair the national security. Notice of any such additional action taken shall be published in the **Federal Register**; or

(2) Not take any additional action. This determination and the reasons on which it is based, shall be published in the **Federal Register**.

8. A new section 705.12 is added to read as follows:

§ 705.12 Disposition of an investigation and report to the Congress.

(a) Upon the disposition of each request, application, or motion made under this part, a report of such disposition shall be submitted by the Secretary to the Congress and published in the **Federal Register**.

(b) As required by Section 232(e) of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862(c)), the President shall submit to the Congress an annual report on the operation of this part.

Dated: June 5, 1998.

Iain S. Baird,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 98-15411 Filed 6-9-98; 8:45 am]

BILLING CODE 3510-JT-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 510****Animal Drugs, Feeds, and Related Products; Change of Sponsor Name**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name from Boehringer Ingelheim Animal Health, Inc., to Boehringer Ingelheim Vetmedica, Inc.

EFFECTIVE DATE: June 10, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 65406, has informed FDA of a change of sponsor name to Boehringer Ingelheim Vetmedica, Inc. Accordingly, the agency is amending 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for "Boehringer Ingelheim Animal Health, Inc." and by alphabetically adding a new entry for "Boehringer Ingelheim Vetmedica, Inc."; and in the table in paragraph (c)(2) in the entry for "000010" by removing the sponsor name "Boehringer Ingelheim Animal Health, Inc." and adding in its place "Boehringer Ingelheim Vetmedica, Inc."

Dated: May 22, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98-15481 Filed 6-9-98; 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; Fenbendazole Paste

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 a supplemental new animal drug application (NADA) filed by Hoechst Roussel Vet. The supplemental NADA provides for expanding the indications to include treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae.

EFFECTIVE DATE: June 10, 1998.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1612.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 120-648 that provides for oral administration of Panacur® and Safe-Guard® (fenbendazole 10 percent) paste to horses. The product is currently approved for use concomitantly with an approved form of trichlorfon. Trichlorfon is approved for the treatment of stomach bots (*Gasterophilus spp.*) in horses. The supplemental NADA provides for expanding the indications to include treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae when administered at 10 milligrams per kilogram per day for 5 consecutive days. The supplemental NADA is approved as of April 20, 1998, and the regulations are amended in 21 CFR 520.905c(d)(1)(iii) to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, 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, this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning April 20, 1998, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

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.

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 520.905c is amended by adding paragraph (d)(1)(iii) to read as follows:

§ 520.905c Fenbendazole paste.

* * * * *

(d) * * *

(1) * * *

(iii)(a) *Amount.* 4.6 milligrams per pound of body weight (10 milligrams per kilogram) daily for 5 consecutive days.

(b) *Indications for use.* For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third stage (hypobiotic), late third stage, and fourth stage larvae in horses.

(c) *Limitations.* (Consult your veterinarian for assistance in the diagnosis, treatment, and control of encysted mucosal cyathostomes). Do not use in horses intended for food.

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Dated: May 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-15480 Filed 6-9-98; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 982

[Docket No. FR-4054-C-03]

RIN 2577-AB63

Section 8 Certificate and Voucher Programs Conforming Rule; Correction

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.