Dated: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11516 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Medetomidine Hydrochloride Injection; 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 approval of a new animal drug application (NADA) filed by Orion Corp. ORION–FARMOS. The NADA provides for the use of medetomidine hydrochloride injection in dogs for its sedative and analgesic properties. The regulations are also amended to reflect a change of sponsor name.

EFFECTIVE DATE: May 9, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Orion Corp. ORION–FARMOS, (formerly Orion Corp. FARMOS), P.O. Box 425, SF–20101 Turku, Finland, filed NADA 140–999, which provides for intravenous or intramuscular use of Domitor® (medetomidine hydrochloride) injection as a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The drug product is available by prescription. The application is approved as of March 19, 1996, and the regulations are amended in part 522 (21 CFR part 522) by adding new § 522.1335 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Additionally, the firm has informed FDA that it has changed its corporate name from Orion Corp. FARMOS to Orion Corp. ORION–FARMOS. Accordingly, the agency is also amending 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 19, 1996, because no active ingredient (including any ester or salt of the active ingredient) of the drug has been approved in any other application under section 512(b)(1) of the act.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

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

21 CFR Part 522

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (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 sponsor name ''Orion Corp. FARMOS, Research and Development, Pharmaceuticals,'' and by adding in its place ''Orion Corp. ORION–FARMOS'', and in the table in paragraph (c)(2) in the entry for ''052483'' by removing the sponsor name ''Orion Corp. FARMOS, Research and Development, Pharmaceuticals,'' and adding in its place ''Orion Corp. ORION–FARMOS''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

4. New § 522.1335 is added to read as follows:

§ 522.1335 Medetomidine hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 1.0 milligram of medetomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use.* As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations.* Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severly debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: April 15, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–11511 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Halofuginone Hydrobromide, Bacitracin Methylene Disalicylate

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 new animal drug application (NADA) filed by Hoechst-Roussel Agri-Vet Co. The NADA provides for using approved single ingredient Type A medicated articles to make Type C medicated turkey feeds containing halofuginone hydrobromide and bacitracin methylene disalicylate.

EFFECTIVE DATE: May 9, 1996

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1607.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., Route 202–206, P.O. Box 2500, Somerville, NJ 08876–1258, has filed NADA 140–919, which provides for use of approved Stenorol® (2.72 grams of halofuginone hydrobromide per pound of Type A article) and approved BMD® (30, 50, or 60 grams of bacitracin methylene disalicylate per pound) to make Type C medicated turkey feeds containing 1.36 to 2.72 grams per ton (g/t) halofuginone hydrobromide and 10 to 50 g/t bacitracin methylene disalicylate, for prevention of coccidiosis in growing turkeys caused by *Eimeria adenoeides, E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain.

The NADA 140–919 is approved as of May 9, 1996, and the regulations are amended in § 558.265(c)(2)(ii) (21 CFR 558.265(c)(2)(ii)) 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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.

This approval is for use of single ingredient Type A medicated articles to make Type C medicated feeds. Halofuginone hydrobromide is a Category II drug which, as provided in § 558.4, requires an approved form FDA 1900 for making a Type C medicated feed. Therefore, use of halofuginone hydrobromide and bacitracin methylene disalicylate Type A medicated articles to make a combination drug Type C medicated feed as provided in NADA 140–919 requires an approved form FDA 1900.

The agency has determined under 21 CFR 25.24(d)(1)(ii) 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for use in food-producing animals qualifies for 3 years of marketing exclusivity beginning May 9, 1996, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.265 is amended by adding new paragraph (c)(2)(ii) to read as follows:

§ 558.265 Halofuginone hydrobromide.

* * * * *

(c) * * *

(2) * * *

(ii) *Amount per ton*. Halofuginone hydrobromide 1.36 to 2.72 grams plus bacitracin methylene disalicylate 10 to 50 grams.

(A) *Indications for use*. For prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis*, and *E. gallopavonis*, and for increased rate of weight gain in growing turkeys.

(B) *Limitations*. Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl. Keep out of lakes, ponds, and streams. Halofuginone is toxic to fish and aquatic life. Halofuginone is an irritant to eyes and skin. Avoid contact with skin, eyes, or clothing.

Dated: April 26, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–11514 Filed 5–8–96; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 24

[T.D. ATF–371; RE: Notice Nos. 800 and 805]

RIN: 1512–AB26

Materials and Processes Authorized for the Production of Wine and for the Treatment of Juice, Wine and Distilling Material (93F–059P)

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

ACTION: Final rule (Treasury decision).

SUMMARY: This final rule amends the wine regulations in 27 CFR Part 24 to add or modify the use of 3 wine treating processes and to add the use of 1 new wine treating material. The use of these new or modified wine treating processes and materials has been found to be acceptable in ''good commercial practice'' in the production, cellar treatment, and finishing of wine, pursuant to the provisions of Section 5382 of the Internal Revenue Code of 1986, since their use will not alter vinous character or pose any health, safety, or consumer deception problems.

EFFECTIVE DATE: July 8, 1996.

FOR FURTHER INFORMATION CONTACT: Robert White, Coordinator, Wine, Beer and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226 (202–927–8230).

SUPPLEMENTARY INFORMATION:

Background

Several members of the wine industry petitioned ATF for approval of the use of 3 wine treating processes and 1 wine treating material in the production, cellar treatment, and/or finishing of wine. Only one of the processes, the spinning cone column, is new and would be used to reduce the ethyl alcohol content of wine or to remove off flavors in wine. The other two processes are not new but either would be used in combination or would be used for a different purpose or at a different limitation than previously authorized. The processes to be used in combination are reverse osmosis and ion exchange