What About Alternative Methods of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Standards Office, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4110; facsimile: (816) 329–4090.

(1) For information on any already approved alternative methods of compliance, contact Mr. Paul Pellicano, Aerospace Engineer (Icing Specialist), Atlanta Aircraft Certification Office, FAA, One Crown Center, 1895 Phoenix Boulevard, Suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6064; facsimile: (770) 703–6097.

(2) Alternative methods of compliance approved in accordance with AD 2003–22–07, which is revised by this AD, are approved as alternative methods of compliance with this AD.

Issued in Kansas City, Missouri, on February 24, 2004.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–4512 Filed 3–1–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Levamisole Powder for Oral Solution

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 Schering-Plough Animal Health Corp. The supplemental NADA revises the description of various internal parasites in labeling for levamisole powder, used to make a drench solution for oral administration to cattle and sheep.

DATES: This rule is effective March 2, 2004.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *jmessenh@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 112–051 for LEVASOLE (levamisole) Soluble Drench Powder revising the description of various internal parasites in labeling for levamisole powder, used to make a drench solution for oral administration to cattle and sheep. The supplemental NADA is approved as of December 23, 2003, and the regulations are revised in 21 CFR 520.1242a to reflect the approval and a current format. 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 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 Division of Dockets Management (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.

The agency has determined under 21 CFR 25.33(a)(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 520.1242a is revised to read as follows:

§ 520.1242a Levamisole powder for oral solution.

(a) *Specifications.* Each package of powder contains 9.075, 11.7, 18.15, 46.8, or 544.5 grams (g) levamisole hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) for use as follows:

(1) No. 000061 for use of 46.8- and 544.5-g packages as in paragraph (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section; for 11.7-, 46.8-, and 544.5-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for an 18.15-g package as in paragraph (e)(3) of this section.

(2) No. 053501 for use of a 46.8-g package as in paragraph (e)(1)(i), (e)(1)(ii)(a), and (e)(1)(iii) of this section; for 11.7- and 46.8-g packages as in paragraph (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section; and for 9.075- and 18.15-g packages as in paragraph (e)(3) of this section.

(3) No. 057561 for use of 46.8- and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) and (e)(2)(i), (e)(2)(ii)(A), and (e)(2)(iii) of this section.

(4) No. 059130 for use of an 18.15-g package as in paragraph (e)(3) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use.* It is used as an anthelmintic as follows:

(1)*Cattle*—(i) *Amount.* 8 milligrams per kilogram (mg/kg) body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*); intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus placei, Ostertagia ostertagi, Trichostrongylus axei*); intestinal worms (*T. longispicularis, Cooperia oncophora, C. punctata, Nematodirus spathiger, Bunostomum phlebotomum, Oesophagostomum radiatum*); and lungworms (*Dictyocaulus viviparus*).

(iii) *Limitations.* Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult your veterinarian before using in severely debilitated animals.

(2) *Sheep*—(i) *Amount.* 8 mg/kg body weight as a drench.

(ii) *Indications for use*—(A) Effective against the following nematode infections: Stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*); intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia*); and lungworms (*Dictyocaulus*).

(B) Effective against the following adult nematode infections: Stomach worms (*Haemonchus contortus, Trichostrongylus axei, Teladorsagia circumcincta*); intestinal worms (*Trichostrongylus colubriformis, Cooperia curticei, Nematodirus spathiger, Bunostomum trigonocephalum, Oesophagostomum columbianum, Chabertia ovina*), and lungworms (*Dictyocaulus filaria*).

(iii) *Limitations*. Do not slaughter for food within 72 hours of treatment. Conditions of constant helminth exposure may require retreatment 2 to 4 weeks after the first treatment. Consult veterinarian before using in severely debilitated animals.

(3) *Swine*—(i) *Amount*. 8 mg/kg body weight in drinking water.

(ii) *Indications for use*. Effective against the following nematode infections: Large roundworms (*Ascaris suum*), nodular worms (*Oesophagostomum* spp.), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp*.).

(iii) *Limitations*. Do not administer within 72 hours of slaughter for food. Pigs maintained under conditions of constant exposure to worms may require retreatment within 4 to 5 weeks after the first treatment. Consult your veterinarian before administering to sick swine.

Dated: February 12, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–4518 Filed 3–1–04; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–7629–2]

RIN 2060–AG12

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency.

ACTION: Notice of denial of petition.

SUMMARY: This action notifies the public that the Agency received a petition pursuant to section 612(d) of the Clean Air Act, under the Significant New Alternatives Policy (SNAP) Program, and that EPA is denying the petition. SNAP implements section 612 of the Clean Air Act Amendments of 1990, which requires EPA to evaluate substitutes for ozone-depleting substances (ODSs) and to regulate the use of substitutes where other alternatives exist that reduce overall risk to human health and the environment. Through these evaluations, EPA generates lists of acceptable and unacceptable substitutes for each of the major industrial use sectors that use ODSs, including the refrigeration and air-conditioning sector. OZ Technology, Inc. submitted HC–12a, previously referenced as Hydrocarbon Blend B, as a CFC–12 substitute in a variety of end-uses on July 19, 1994. In a June 13, 1995 final SNAP rulemaking (60 FR 31092), EPA found the use of HC–12a unacceptable as a substitute for CFC–12 in all end-uses other than industrial process refrigeration. This determination was based on a lack of adequate data demonstrating that HC–12a could be used safely in these end-uses; the most recent petition from OZ does not provide any additional information to address this issue. In addition, numerous other acceptable alternatives to ODSs exist in these end-uses.

EFFECTIVE DATE: March 2, 2004.

ADDRESSES: Information relevant to this notice is contained in Air Docket A–91–42, 1301 Constitution Avenue, NW., U.S. Environmental Protection Agency, Mail Code 6102T; Washington, DC 20460. The docket reading room is located at the address above in room B102 in the basement. Reading room telephone: (202) 566–1744, facsimile: (202) 566–1749 Air docket staff telephone: (202) 566–1742 and facsimile: (202) 566–1741 You may inspect the docket between 8:30 a.m. and 4:30 p.m. weekdays. As provided in 40 CFR Part 2, a reasonable fee may be charged for photocopying.

FOR FURTHER INFORMATION CONTACT: Dave Godwin by telephone at (202) 343–9324, by facsimile at (202) 343–2316, by e-mail at *Godwin.Dave@epa.gov,* or by mail at U.S. Environmental Protection Agency, Mail Code 6205J, Washington, DC 20460.

For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the original SNAP rulemaking published in the **Federal Register** on March 18, 1994 (59 FR 13044). Notices and rulemakings under the SNAP program, as well as other EPA publications on protection of stratospheric ozone, are available from EPA's Ozone Depletion World Wide Web site at *http://www.epa.gov/ozone/* including the SNAP portion at *http://www.epa.gov/ozone/snap/.*

SUPPLEMENTARY INFORMATION: Since the publication of this unacceptability determination, OZ Technology, Inc. (''OZ'') has petitioned EPA four times. The following table provides information about each of the previous petitions and EPA's denials.

Item	Date	Location (within docket A–91–42)	FR Notice
OZ Petition 1	November 4, 1994	VI–D–75	N/A
EPA Denial of Petition 1	July 25, 1995	VI–C–7	60 FR 49407
OZ Petition 2	December 5, 1995	VI–D–135	N/A
EPA Denial of Petition 2	August 30, 1996	VI–C–20	61 FR 51018
OZ Petition 3	May 1, 1998	VI–D–229	N/A
EPA Denial of Petition 3	November 13, 1998	VI–C–28	64 FR 3272

On July 8, 2003, OZ petitioned EPA for the fourth time, once again requesting that EPA remove HC–12a from the unacceptable list and add it to the acceptable list as an ODS substitute in all refrigeration and air-conditioning end-uses, except the industrial process refrigeration end-use, where EPA has already found the use of HC–12a as acceptable. The petition is in Air Docket A–91–42, file number VI–D–306. On January 14, 2004, EPA notified the company that it has denied the petition on the basis that the information included in the petition did not adequately address safety issues regarding the use of HC–12a as a CFC–12 substitute in the subject end-uses. The denial and the accompanying documentation are in Air Docket A–91–42, file number VI–C–31. This Notice