

Inc. The supplemental NADA provides for extended use of doramectin in cattle for persistent control of nematodes including *Haemonchus placei* for 14 days after treatment.

**EFFECTIVE DATE:** March 19, 1999.

**FOR FURTHER INFORMATION CONTACT:** Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7575.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 141-061 that provides for subcutaneous and intramuscular use of Dectomax® (doramectin) 1 percent injectable solution in cattle to control infections and to protect from reinfection with *H. placei* for 14 days after treatment. The persistent use is in addition to the approved use in cattle for treatment and control of various gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* for 14 days, *Ostertagia ostertagi* for 21 days, and *Cooperia punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

Supplemental NADA 141-061 is approved as of February 1, 1999, and the regulations are amended in 21 CFR 522.770(d)(1)(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 21 CFR part 20 and 514.11(e)(2)(ii), a summary of data and information submitted to support approval of the supplemental 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning February 1, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental application and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin injection to control

infections and to protect cattle from reinfection with *H. placei* for 14 days after treatment.

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.

#### List of Subjects in 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 part 522 is amended as follows:

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

**Authority:** 21 U.S.C. 360b.

#### § 522.770 [Amended]

2. Section 522.770 *Doramectin* is amended in paragraph (d)(1)(ii) by adding after "*Cooperia oncophora*" the phrase "and *Haemonchus placei*".

Dated: February 26, 1999.

**Margaret Ann Miller,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Propofol Injection

**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 provides for expanding the indications to include the use of propofol in cats.

**EFFECTIVE DATE:** March 19, 1999.

**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:** Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed supplemental NADA 141-070 that provides for intravenous use in cats of Rapinovet Anesthetic Injection (each milliliter contains 10 milligrams of propofol). The product was previously approved for use in dogs. The drug is used as a single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to affect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics. The drug is limited to use by or on the order of a licensed veterinarian. The supplemental NADA is approved as of January 14, 1999, and the regulations are amended in 21 CFR 522.2005 by revising paragraph (b) and by adding paragraph (c)(2) to reflect the approval. The basis of approval is provided 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for a 3-year period of marketing exclusivity beginning January 14, 1999, because the supplement application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species (cats) for which the supplemental application was approved.

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 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 part 522 is amended as follows:

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

**Authority:** 21 U.S.C. 360b.

2. Section 522.2005 is amended by revising paragraph (b) and by adding paragraph (c)(2) to read as follows:

**§ 522.2005 Propofol injection.**

\* \* \* \* \*

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use as in paragraphs (c)(1) and (c)(2) of this section. See No. 000074 in § 510.600(c) of this chapter for use as in paragraph (c)(1) of this section.

(c) \* \* \*

(2) *Cats.* (i) The drug is indicated for use as an anesthetic as follows: As a single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to effect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) The drug is administered by intravenous injection as follows: For induction of general anesthesia without the use of preanesthetics the dosage is 8.0 to 13.2 milligrams per kilogram (3.6 to 6.0 milligrams per pound). For the maintenance of general anesthesia without the use of preanesthetics the dosage is 1.1 to 4.4 milligrams per kilogram (0.5 to 2.0 milligrams per pound). The use of preanesthetic medication reduces propofol dose requirements.

(iii) Adequate data concerning safe use of propofol in pregnant and breeding cats have not been obtained. Doses may need adjustment for geriatric or debilitated patients. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: February 23, 1999.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*  
[FR Doc. 99-6668 Filed 3-18-99; 8:45 am]

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**DEPARTMENT OF STATE**

**22 CFR Part 41**

[Public Notice 2992]

**Bureau of Consular Affairs; Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended; Photograph Requirement**

**AGENCY:** Bureau of Consular Affairs, DOS.

**ACTION:** Final rule.

**SUMMARY:** The Department has replaced the Burroughs visa with a machine-readable visa (MRV). Since the MRV displays a digitized photo of the visa recipient, the Department is amending the nonimmigrant visa regulations to require all applicants for nonimmigrant visas to present photographs. The regulations are also amended to allow photographs of persons wearing head coverings, provided that enough of the face is uncovered so as to establish identity.

**EFFECTIVE DATE:** March 19, 1999.

**FOR FURTHER INFORMATION CONTACT:** Pam Chavez, Legislation and Regulations Division, Visa Services, Bureau of Consular Affairs, Department of State, 202-663-1206.

**SUPPLEMENTARY INFORMATION:** Effective April 1, 1994, the Department instructed all Foreign Service posts to cease issuing Burroughs visas, which were stamps placed in the passport. Foreign Service posts worldwide now issue only machine-readable visas (MRVs), a more technologically advanced and secure type of visa with a digitized photo of the applicant. The MRV is also inserted in the passport. The Department has, therefore, amended the regulations at 22 CFR 41.105(a)(3) to eliminate the waiver of photographs authorized in paragraphs (i), (ii) and (iii).

**Final Rule**

This rule is being promulgated as a final rule pursuant to the "good cause" provision of 5 U.S.C., sec. 553(b). Notice and comment serve no purpose in light of the fact that visas can no longer be issued without a photograph. This rule is not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. It is not a major rule. This rule imposes no reporting or recordkeeping action from the public requiring the approval of the Office of Management and Budget under the Paperwork Reduction Act. This rule complies with requirements of E.O. 12988.

**List of Subjects in 22 CFR Part 41**

Aliens, Nonimmigrants, Passport and visas.

In view of the foregoing 22 CFR part 41 is amended as follows:

**PART 41—[AMENDED]**

1. The authority citation for part 41 continues to read as follows:

**Authority:** 8 U.S.C. 1104.

2. Revise paragraph (a)(3) of § 41.105 and remove the undesignated paragraph following it to read as follows:

**§ 41.105 Supporting documents and fingerprinting.**

(a) \* \* \*

(3) *Photographs required.* Every applicant for a nonimmigrant visa must furnish a photograph in such numbers as the consular officer may require. Photographs must be a reasonable likeness, 1½ by 1½ inches in size, unmounted, and showing a full, front-face view of the applicant against a light background. At the discretion of the consular officer, head coverings may be permitted provided they do not interfere with the full, front-face view of the applicant. The applicant must sign (full name) on the reverse side of the photographs. The consular officer may use a previously submitted photograph, if he is satisfied that it bears a reasonable likeness to the applicant.

Dated: March 11, 1999.

**Mary A. Ryan,**

*Assistant Secretary for Consular Affairs.*

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**24 CFR Part 941**

[Docket No. FR-4443-F-05]

**Public Housing Development Rule: Information Collection Approval Numbers**

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

**ACTION:** Final rule.

**SUMMARY:** This rule revises the chart in the public housing development regulations showing the numbers assigned by the Office of Management and Budget (OMB) approving information collections contained throughout those regulations. This revision is necessary to bring the chart in conformity with the actual approval numbers, and to assure that the