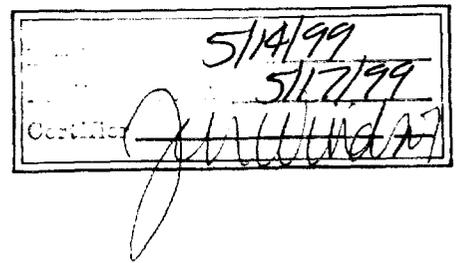


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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin; Ivermectin and Clorsulon

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 two supplemental new animal drug applications (NADA's) filed by Merial Ltd. One supplement provides for use of ivermectin injection, and the other provides for the use of ivermectin and clorsulon injection, for 28-day persistent control of lungworms in cattle. In addition, a tolerance for ivermectin residues in cattle muscle is established.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, is sponsor of NADA 128-409 that provides for use of Ivomec® Injection (1 percent ivermectin) and NADA 140-833 that provides for use of Ivomec® Plus Injection (1 percent ivermectin and 10 percent clorsulon) in cattle. The NADA's provide for use of the drugs for the treatment and control of gastrointestinal roundworm, lungworm, grub, lice, and mange mite infections, to control infection and to protect from reinfection with *Dictyocaulus viviparus* and *Ostertagia ostertagi* for 21 days after treatment, and *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, *C. oncophora*,

and *Oesophagostomum radiatum* for 14 days after treatment. Also, NADA 140–833 provides for treatment and control of liver flukes. Merial Ltd. filed supplements to both NADA's that amend their use to provide for control of infection and protection from reinfection of *Dictyocaulus viviparus* for 28 days after treatment. The supplements are approved as of April 1, 1999, and the regulations are amended in 21 CFR 522.1192(d)(2)(ii) and 522.1193(d)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has revised the tolerances for residues of ivermectin to establish an acceptable daily intake and a swine muscle tolerance (63 FR 54352, October 9, 1998). At this time, FDA further amends the ivermectin residue tolerances in 21 CFR 556.344 to establish a cattle muscle tolerance.

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 these applications 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)), these supplemental approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning April 1, 1999, because the supplements contain substantial evidence of 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 supplements and conducted or sponsored by the applicant. Exclusivity applies only to the additional indication for persistent effectiveness.

FDA has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are 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.

§ 522.1192 [Amended]

2. Section 522.1192 *Ivermectin injection* is amended in paragraph (d)(2)(ii) in the last sentence by removing “*D. viviparus* and” and adding in its place “*D. viviparus* for 28 days after treatment,”.

3. Section 522.1193 is amended in paragraph (d)(2) by revising the last sentence to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) * * * It is also used to control infections of *D. viviparus* for 28 days after treatment, *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

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Ruth P.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

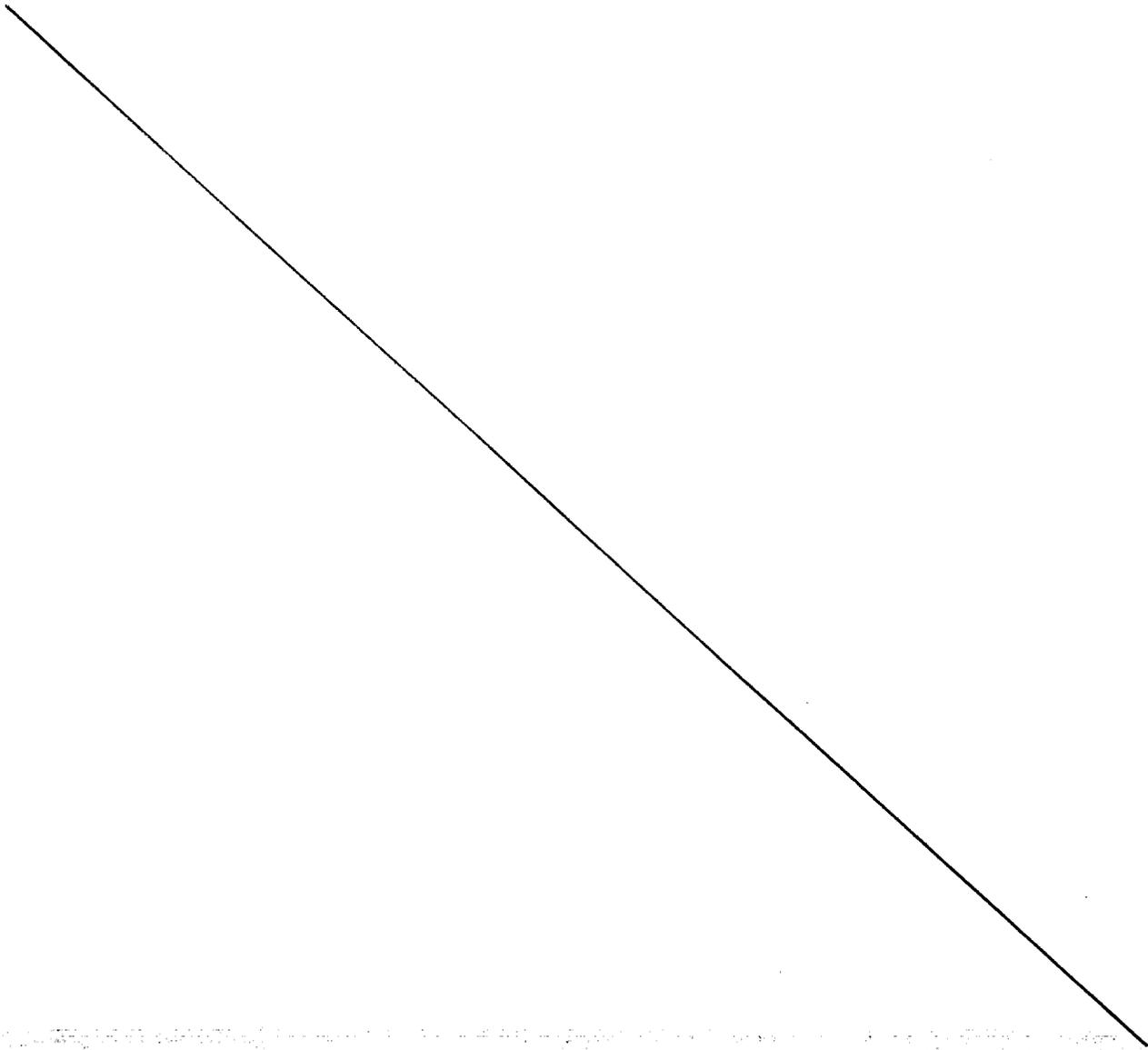
4. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

5. Section 556.344 is amended by adding paragraph (b)(2)(ii) to read as follows:

§ 556.344 Ivermectin.

* * * * *



(b) * * *

(2) * * *

(ii) *Cattle*. 10 parts per billion.

Dated: May 3, 1999

May 3, 1999

Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug
Evaluation
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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