4. On page 40331, in the first column, under the caption ''*Description*:'', in line 10, ''(b) and '' is added between ''101.13'' and ''(q)(5)''. On the same page, in the second column, in the first full paragraph, in line 25, ''(b) and '' is added between ''101.13'' and ''(q)(5)'', and in the same paragraph, the first 23 lines are removed. The paragraph now begins with ''Once it becomes effective''.

5. On page 40332, in the second column, amendatory item ''3.'' is corrected to read as follows:

3. Section 101.13 is amended by revising the introductory text of paragraphs (b) and (q)(5) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) A claim that expressly or implicitly characterizes the level of a nutrient (a nutrient content claim) of the type required in nutrition labeling under § 101.9 may not be made on the label or in labeling of foods unless the claim is made in accordance with this section and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

* * * * *

(q) * * *

(5) A nutrient content claim used on food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

* * * * *

Dated: December 13, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–32428 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Bolus

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 Merck Research Laboratories. The NADA provides for use of an ivermectin-containing, sustained-release bolus in cattle for treatment and control for approximately 135 days of certain internal and external parasitic infections throughout the grazing season.

EFFECTIVE DATE: December 23, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065–0914, filed NADA 140–988, which provides for the use of Ivomec® (1.72 grams ivermectin) Sustained-Release Bolus for Cattle for the treatment and control of certain gastrointestinal roundworm, lungworm, mange mite, sucking lice, cattle grub, and tick infections in cattle weighing at least 275 pounds (lb) (125 kilograms (kg)) but not more than 660 lb (300 kg) of body weight on the day of administration. The NADA is approved as of November 18, 1996, and the regulations are amended in 21 CFR part 520 by adding new § 520.1197 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 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning November 18, 1996, because the application contains substantial evidence of the effectiveness of the drug involved, 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 application and conducted or sponsored by the applicant.

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

2. New § 520.1197 is added to read as follows:

§ 520.1197 Ivermectin sustained-release bolus.

(a) *Specifications.* Each sustained-release bolus contains 1.72 grams of ivermectin.

(b) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Conditions of use in ruminating calves*—(1) *Amount.* Administer one bolus per calf weighing at least 275 pounds (lb) (125 kilograms (kg)) and not more than 660 lb (300 kg) on the day of administration.

(2) *Indications.* For treatment and control, throughout the grazing season (approximately 135 days), of gastrointestinal roundworms *Haemonchus placei, Ostertagia ostertagi* (including inhibited fourth-stage larvae), *Trichostrongylus axei, T. colubriformis, Cooperia* spp., *Nematodirus helvetianus, Bunostomum phlebotomum, Oesophagostomum radiatum;* lungworms *Dictyocaulus viviparus;* grubs *Hypoderma* spp.; sucking lice *Linognathus vituli, Solenopotes capillatus;* mange mites *Psoroptes ovis, Sarcoptes scabiei,* and ticks *Amblyomma americanum.*

(3) *Limitations.* The bolus was specifically designed for use in cattle; do not use in other animal species. Calves must be ruminating and older than 12 weeks of age. Do not administer to calves weighing less than 275 lb (125 kg). Do not administer a damaged bolus. Because a milk withdrawal time has not been established, do not use in female dairy cattle of breeding age. Do not slaughter cattle within 180 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Dated: December 12, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32431 Filed 12–20–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Oxytetracycline

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 Pfizer Animal Health. The supplemental NADA provides for revised tolerances for residues of oxytetracycline in edible tissues.

EFFECTIVE DATE: December 23, 1996.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1623.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 113–232, which provides for the use of Liquamycin® LA–200® (oxytetracycline) sterile suspension for injection in beef cattle, beef calves, nonlactating dairy cattle, dairy calves, and swine for the indications for use as in 21 CFR 522.1662a.

The supplement provides for a change in the tolerance levels specified in § 556.500 (21 CFR 556.500) for oxytetracycline residues in edible tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, and swine. Review of the supplement involved a reevaluation of the data and information in the original approval using criteria in the ''Human Food Safety Guideline for Antimicrobial Drugs.'' The supplement is approved as of May 31, 1996, and the regulation in § 556.500 is revised to reflect the approval.

In evaluating this supplement, FDA's Center for Veterinary Medicine (CVM) considered the cumulative effects of all tetracyclines approved for use as new animal drugs because all tetracycline drugs have a similar end point of toxicological concern, i.e., an effect on the intestinal microflora. Based on the cumulative effect, the acceptable daily intake (ADI) was established for total tetracycline activity at 1.5 milligrams per person per day. Forty percent of that ADI is being assigned to edible tissues and 60 percent of the ADI is reserved for milk. Based on this evaluation, CVM has established the revised tolerance for residues of all tetracycline new animal drugs (including chlortetracycline, oxytetracycline, and tetracycline) to 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney. As such, § 556.500 has been amended to provide that for oxytetracycline, tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline at 2 ppm in muscle, 6 ppm in liver, and 12 ppm in kidney and fat.

Although approval of Pfizer's supplement did not require submission of new safety or effectiveness data, a summary of data and information used to support approval of this supplement as described in 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii) 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 (21 U.S.C. 360b(c)(2)(F)(iii)), this supplement does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

FDA has determined under 21 CFR 25.24(d)(1)(i) 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.

Because the revised tolerance approved in this supplement for oxytetracycline is based on the total tetracycline activity, it, in effect, revises the tolerances for chlortetracycline and tetracycline. Therefore, FDA has also revised 21 CFR 556.150 (chlortetracycline) and 556.720 (tetracycline) to be consistent with the new tolerance for oxytetracycline based on the total tetracycline activity.

List of Subjects in 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 part 556 is amended as follows:

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

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

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

2. Section 556.150 is revised to read as follows:

§ 556.150 Chlortetracycline.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, as follows:

(a) 2 parts per million (ppm) in muscle.

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

3. Section 556.500 is revised to read as follows:

§ 556.500 Oxytetracycline.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows:

(a) 2 parts per million (ppm) in muscle.

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

4. Section 556.720 is revised to read as follows:

§ 556.720 Tetracycline.

Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues of calves, swine, sheep, chickens, and turkeys, as follows:

(a) 2 parts per million (ppm) in muscle.

(b) 6 ppm in liver.

(c) 12 ppm in fat and kidney.

Dated: December 9, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32430 Filed 12–20–96; 8:45 am]

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