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.

§ 522.1182 [Amended]

2. Section 522.1182 *Iron dextran complex injection* is amended in paragraph (b)(2)(i) by removing ''No. 000010'' and adding in its place ''Nos. 000010 and 059130''.

Dated: September 23, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–26648 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride Sterile Suspension

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 Pharmacia & Upjohn Co. One supplemental NADA provides for veterinary prescription use of ceftiofur hydrochloride sterile suspension for intramuscular or subcutaneous injection in cattle for treatment of bovine respiratory disease and acute bovine interdigital necrobacillosis. The second supplemental NADA provides for a revised label warning against use in veal calves.

EFFECTIVE DATE: October 6, 1998.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1659.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed two supplements to NADA 140–890. One supplement provides for veterinary prescription use of Excenel® (ceftiofur hydrochloride) Sterile Suspension for intramuscular or subcutaneous injection in cattle for treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Pasteurella haemolytica, P. multocida*, and *Haemophilus somnus* and acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*. This supplemental NADA is approved as of July 26, 1998. The second supplemental NADA provides for a revised label warning against use in veal calves and is approved as of August 18, 1998. The regulation is amended in 21 CFR part 522.314 to reflect the approvals. The basis for approval is discussed in the freedom of information summary.

In addition, due to injection site residues following subcutaneous use of this product in cattle, 21 CFR 556.113 is amended to establish tolerances for residues of ceftiofur in edible tissues of treated cattle. Also, the regulation is amended to establish an acceptable daily intake (ADI) for total ceftiofur residues. The ADI represents the total amount of drug residue that can safely be consumed by humans every day.

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 21 U.S.C. 360b(c)(2)(F)(iii), this approval for food producing animals qualifies for 3 years of marketing exclusivity beginning July 26, 1998, because the supplemental application 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 the approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species (cattle) for which the supplemental application is approved.

The agency has determined under 21 CFR 25.33(d)(5) 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

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.

2. Section 522.314 is amended by adding paragraph (d)(2) to read as follows:

§ 522.314 Ceftiofur hydrochloride sterile suspension.

* * * * *

(d) * * *

(2) *Cattle*— (i) *Dosage*. 1.1 to 2.2 milligrams per kilogram (0.5 to 1.0 milligrams per pound) of body weight, at 24-hour intervals for 3 to 5 consecutive days. In addition, for bovine respiratory disease, administer 2.2 milligrams per kilogram (1.0 milligram per pound) of body weight every other day on days 1 and 3 (48-hour interval).

(ii) *Indications for use*. For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Pasteurella haemolytica, P. multocida*, and *Haemophilus somnus* and acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations*. For intramuscular or subcutaneous use only. Do not inject more than 15 milliliters at each intramuscular injection site. Do not slaughter treated cattle for 48 hours (2 days) after last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

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

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

4. Section 556.113 is revised to read as follows:

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of ceftiofur is 30 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine, poultry, and sheep.* A tolerance for residues of ceftiofur in edible tissue is not required.

(2) *Cattle.* Tolerances are established for residues of desfuroylceftiofur (marker residue) in edible cattle tissues at 8 parts per million in kidney (target tissue), 2 parts per million in the liver, 1 part per million in muscle, and 100 parts per billion in milk.

Dated: September 23, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–26650 Filed 10–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 97F–0522]

Food Additives Permitted in Feed and Drinking Water of Animals; Formaldehyde

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution), at a rate of 5.4 pounds (2.5 kilograms) per ton, as an antimicrobial food additive for maintaining animal feeds and feed ingredients *Salmonella* negative for up to 21 days. This action is in response to a food additive petition filed by Anitox Corp. of Buford, GA.

DATES: Effective October 6, 1998; written objections and request for hearing should be submitted by November 5, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Henry E. Ekperigin, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0174.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of February 11, 1998 (63 FR 6945), FDA announced that a food additive petition (animal use) (FAP 2237) had been filed by Anitox Corp., P. O. Box 1929, Buford, GA 30519. The petition proposed that the food additive regulations in § 573.460 *Formaldehyde* (21 CFR 573.460) be amended to provide for the safe use of formaldehyde (37 percent aqueous solution) at a rate of 5.4 pounds per ton of animal feeds and feed ingredients to maintain the animal feeds and feed ingredients free of *Salmonella*. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. No comments have been received.

The sponsor has amended the petition three times since it was originally filed, on March 2, 1998, providing additional data to establish utility of formaldehyde for the intended use; July 14, 1998, providing the proposed wording to be included on the product labeling that indicated formaldehyde treatment maintains complete feed and feed ingredients *Salmonella* negative up to 21 days from date of application; and July 20, 1998, providing information requested by CVM on the Good Laboratory Practice Statement, clarifying the chemical description of the product on the labeling and in the proposed regulation, and modifying the references to environmental authorities on the labeling and in the proposed regulation. The amended petition proposes that § 573.460 be amended to provide for the safe use of formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution), at a rate of 5.4 pounds (2.5 kilograms) per ton, as an antimicrobial food additive for maintaining animal feeds and feed ingredients *Salmonella* negative for up to 21 days.

Data submitted by the sponsor in support of the petition permitted the agency to make an independent evaluation of whether formaldehyde could be safely used to achieve the intended purpose. When included in complete feed or feed ingredients as proposed, formaldehyde will constitute 0.1 percent of the feed or feed ingredient. The sponsor submitted data showing that this level of formaldehyde should not present a human food safety concern. Formaldehyde occurs in animals as a normal metabolite and is rapidly oxidized to formic acid which further metabolizes into carbon dioxide and water. Formaldehyde is currently approved for use in poultry feed at the inclusion level requested by the petitioner.

Also, formaldehyde has been approved for use in feeds for beef and non-lactating dairy cattle (§ 573.460(a)(2)). The level of formaldehyde in feeds manufactured according to the approval under § 573.460(a)(2) can be as high as 0.25 percent. Formaldehyde is exempted from tolerance requirements under 40 CFR 180.1032 when used as a pesticide/fungicide in cereal grains and forages. Furthermore, although formaldehyde has been found in chronic rat studies to be carcinogenic when inhaled continuously at high doses (> 2 ppm), it has *not* been found to be carcinogenic in rodents when orally ingested at high doses (~5 percent) for a lifetime (Ref. 1).

Formalin (formaldehyde 37 percent aqueous solution) can be life threatening if improperly handled. The proposed label for formaldehyde (CAS No. 50–00–0; 37 percent aqueous solution) acknowledges this fact. To further minimize concerns for worker safety, the label contains adequate directions for use, strong cautionary statements about potential carcinogenic and adverse respiratory effects; information about emergency aid in case of inhalation, ingestion or skin or eye contact, and a contact address and telephone number for reporting adverse reactions experienced by users or to request a copy of the material safety data sheet (MSDS). The label also contains a statement that ''Formaldehyde is subject to SARA Title III, Section 313 reporting'' (Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations). The petition contains assurances by the sponsor that the proposed label will be placed on all containers of the product. However, because formaldehyde is nonproprietary, FDA will include these requirements in the amended formaldehyde food additive regulation. That will enable others marketing formaldehyde to be informed of the requirements and to comply with them.

The petition also includes satisfactory information about the chemical identity of formaldehyde and indicates that formaldehyde will achieve its intended effect in a manner that is safe to the animals consuming the treated products.