§ 179.41 Pulsed light for the treatment of food.

Pulsed light may be safely used for treatment of foods under the following conditions:

(a) The radiation sources consist of xenon flashlamps designed to emit broadband radiation consisting of wavelengths covering the range of 200 to 1,100 nanometers (nm), and operated so that the pulse duration is no longer than 2 milliseconds (msec);

(b) The treatment is used for surface microorganism control;

(c) Foods treated with pulsed light shall receive the minimum treatment reasonably required to accomplish the intended technical effect; and

(d) The total cumulative treatment shall not exceed 12.0 Joules/square centimeter (J/cm^2.)

Dated: July 30, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–20853 Filed 8–14–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; Florfenicol 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 new animal drug application (NADA) filed by Schering-Plough Animal Health. The NADA provides for use of florfenicol injectable solution for cattle for the treatment of bovine respiratory disease.

EFFECTIVE DATE: August 15, 1996.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has filed NADA 141–063 Nuflor® Injectable Solution (300 milligrams florfenicol per milliliter) for intramuscular treatment of cattle for bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, P. multocida,* and *Haemophilus somnus.* The NADA is approved as of May 31, 1996, and the regulations are amended by adding new § 522.955 to reflect the approval. The regulations are also amended to provide for a tolerance for florfenicol residues in cattle in new § 556.283. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for use in food-producing animals qualifies for 5 years of marketing exclusivity beginning May 31, 1996, because the application is for a new animal drug, no active ingredient of which has been approved in any other application.

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

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

2. New § 522.955 is added to read as follows:

§ 522.955 Florfenicol solution.

(a) *Specifications.* Each milliliter of sterile solution contains 300 milligrams of florfenicol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 20 milligrams per kilogram body weight (3 milliliters per 100 pounds). A second dose should be given 48 hours later.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, P. multocida,* and *Haemophilus somnus.*

(iii) *Limitations.* For intramuscular use only. Do not inject more than 10 milliliters at each site. Injection should be given only in the neck musculature. Do not slaughter within 28 days of last treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. Not for use in veal calves, calves under 1 month of age, or calves being fed an all milk diet. Use may cause violative tissue residues to remain beyond the withdrawal time. Not for use in cattle of breeding age. The effect of florfenicol on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

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

4. New § 556.283 is added to read as follows:

§ 556.283 Florfenicol.

The safe concentrations for total florfenicol-related residues in cattle are 2.0 parts per million (ppm) in muscle, 6.0 ppm in liver, and 12.0 ppm in kidney and fat. A tolerance of 3.7 ppm for the marker residue, florfenicol amine, has been established in cattle liver.

Dated: July 25, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–20854 Filed 8–14–96; 8:45 am]

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