a.m. and 4 p.m., Monday through Friday.

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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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: 21 U.S.C. 360b.

2. Section 520.309 is amended in paragraph (a) by removing ''of'' and by revising paragraph (d)(1) to read as follows:

§ 520.309 Carprofen.

* * * * *

(d) * * *

(1) *Amount.* 2 mg per pound (/lb) of body weight once daily or 1 mg/lb twice daily.

* * * * *

Dated: February 5, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–3682 Filed 2–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol

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 supplement provides for changing a pathogen genus from *Pasteurella* to *Mannheimia* on labeling of florfenicol injectable solution.

DATES: This rule is effective February 14, 2002.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569, e-mail: ndas@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, is the sponsor of NADA 141–063 that provides for use of NUFLOR (florfenicol) Injectable Solution in cattle. Schering-Plough Animal Health Corp. filed a supplemental NADA providing for changing a pathogen genus from *Pasteurella* to *Mannheimia* on product labeling. The NADA is approved as of November 8, 2001, and the regulations are amended in § 522.955 (21 CFR 522.955) to reflect the approval. Section 522.955 is also being amended to reflect an updated format. Approval of this supplemental NADA did not require review of safety or effectiveness data; therefore, a freedom of information summary is not required.

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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 522.955 is amended by revising the section heading and by revising paragraphs (a), (d)(1)(i), (d)(1)(ii), and (d)(1)(iii) to read as follows:

§ 522.955 Florfenicol.

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

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 20 mg per kilogram (/kg) of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

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

(B) [Reserved]

(ii) *Amount.* 40 mg/kg body weight as a single subcutaneous injection.

(A) *Indications for use.* As in paragraph (d)(1)(i)(A) of this section; for control of respiratory disease in cattle at high risk of developing BRD associated with *M. (Pasteurella) haemolytica*, *P. multocida*, and *H. somnus*.

(B) [Reserved]

(iii) *Limitations.* Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. 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.

* * * * *

Dated: January 31, 2002.

Claire M. Lathers,

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

[FR Doc. 02–3680 Filed 2–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Zeranol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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 Corp. The NADA provides for use of a subcutaneous ear implant containing zeranol in pasture cattle for increased rate of weight gain. FDA is also amending the regulations to add the acceptable daily intake (ADI) for total residues of zeranol.

DATES: This rule is effective February 14, 2002.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: dbenz@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, filed NADA 141–192 for RALGRO LA (zeranol), a subcutaneous ear implant containing 138 milligrams (mg) zeranol. The implants are used for increased rate of weight gain for up to 210 days in pasture cattle (slaughter, stocker, and feeder steers, and heifers). The application is approved as of November 1, 2001, and the regulations are amended in § 522.2680 (21 CFR 522.2680) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 522.2680 is also being amended to reflect a current format for regulations pertaining to cattle ear implants. This action is being taken to improve the clarity and readability of the regulations. In addition, the regulations are amended in 21 CFR 556.760 by adding the previously established ADI for total residues of zeranol, and editorially, to reflect current format.

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)(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 1, 2001, because the 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 and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA'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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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 522.2680 is amended by revising paragraphs (a), (d)(1)(i), (d)(2)(i), (d)(3)(i), and (d)(3)(ii), and by adding paragraph (d)(4) to read as follows:

§ 522.2680 Zeranol.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

* * * * *

(d) *Conditions of use*—(1) *Beef cattle*—(i) *Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

* * * * *

(2) *Feedlot lambs*—(i) *Amount.* 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.

* * * * *

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

* * * * *

(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)*—(i) *Amount.* 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only.

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 556.760 is amended by redesignating paragraphs (a) and (b) as paragraphs (b)(1), and (b)(2), respectively, by revising newly redesignated paragraph (b)(1), and by adding paragraph (a) to read as follows:

§ 556.760 Zeranol.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of zeranol is 0.00125 milligrams per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle.* Tolerances for residues of zeranol in edible tissues are not needed.

* * * * *

Dated: February 1, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–3681 Filed 2–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Bacitracin Methylene Disalicylate and Zoalene

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.