revising the ''License Exceptions'' section, to read as follows:

8D001 ''Software'' Specially Designed or Modified for the ''Development'', ''Production'' or ''Use'' of Equipment or Materials Controlled by 8A (Except 8A018 or 8A992), 8B or 8C.

* * * * *

License Exceptions

CIV: N/A

TSR: Yes, except for exports or reexports to destinations outside of Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, Portugal, Spain, Sweden, or the United Kingdom of ''software'' specially designed for the ''development'' or ''production'' of equipment controlled by 8A001.b, 8A001.d, or 8A002.o.3.b.

* * * * *

■ 41. In Supplement No. 1 to part 774 (the Commerce Control List), Category 8—Marine, Export Control Classification Number (ECCN) 8E001 is amended by revising the ''License Exceptions'' section, to read as follows:

8E001 ''Technology'' According to the General Technology Note for the ''Development'' or ''Production'' of Equipment or Materials Controlled by 8A (Except 8A018 or 8A992), 8B or 8C.

* * * * *

License Exceptions

CIV: N/A

TSR: Yes, except for exports or reexports to destinations outside of Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Luxembourg, the Netherlands, Portugal, Spain, Sweden, or the United Kingdom of ''technology'' for items controlled by 8A001.b, 8A001.d or 8A002.o.3.b.

* * * * *

■ 42. In Supplement No. 1 to part 774 (the Commerce Control List), Category 9—Propulsion Systems, Space Vehicles and Related Equipment, Export Control Classification Number (ECCN) 9A004 is amended by revising the ''Unit'' paragraph in the List of Items Controlled section, to read as follows:

9A004 Space Launch Vehicles and ''Spacecraft''.

* * * * *

List of Items Controlled

Unit: Number

* * * * *

■ 43. In Supplement No. 1 to part 774 (the Commerce Control List), Category 9—Propulsion Systems, Space Vehicles and Related Equipment, Export Control Classification Number (ECCN) 9B009 is amended by revising the ''Unit'' paragraph in the List of Items Controlled section, to read as follows:

9B009 Tooling Specially Designed for Producing Turbine Engine Powder Metallurgy Rotor Components Capable of Operating at Stress Levels of 60% of Ultimate Tensile Strength (UTS) or More and Metal Temperatures of 873 K (600 °C) or More.

* * * * *

List of Items Controlled

Unit: Number

* * * * *

Dated: April 11, 2008.

Matthew S. Borman,

Acting Assistant Secretary for Export Administration.

[FR Doc. E8–8302 Filed 4–17–08; 8:45 am]

BILLING CODE 3510–33–P

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 new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for use of florfenicol injectable solution for the treatment of bovine respiratory disease.

DATES: This rule is effective April 18, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed NADA 141–265 for veterinary prescription use of NUFLOR GOLD (florfenicol) Injectable Solution by subcutaneous injection in beef and non-lactating dairy cattle for the treatment of bovine respiratory disease. The NADA is approved as of March 21, 2008, and the regulations are amended in 21 CFR 522.955 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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 qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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. Revise § 522.955 to read as follows:

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 300 milligrams (mg) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin.

(2) 300 mg florfenicol in the inactive vehicle n-methyl-2-pyrrolidone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d)(1)(i) and for use of product described in paragraph (a)(2) as in paragraph (d)(1)(ii).

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

(d) *Conditions of use*—(1) *Cattle*—(i) 300 mg/mL florfenicol in 2-pyrrolidone and triacetin (inactive vehicles).

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

(B) *Indications for use*. For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle.

(C) *Limitations*. Do not slaughter within 44 days of last 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.

(ii) 300 mg/mL florfenicol in n-methyl-2-pyrrolidone (inactive vehicle).

(A)(*1*) *Amount*. 20 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later. Alternatively, 40 mg/kg of body weight as a single subcutaneous injection may be used.

(*2*) *Indications for use*. For treatment of 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)(*1*) *Amount*. 40 mg/kg of body weight as a single subcutaneous injection.

(*2*) *Indications for use*. For control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*, *P. multocida*, and *Haemophilus somnus*.

(C) *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.

(2) [Reserved]

Dated: April 4, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–8346 Filed 4–17–08; 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; Insulin

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 Intervet, Inc. The supplemental NADA provides for the veterinary prescription use of an injectable suspension of porcine insulin zinc for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

DATES: This rule is effective April 18, 2008.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 141–236 providing for the veterinary prescription use of VETSULIN (porcine insulin zinc) Suspension for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus. The application also provides for a lower initial dosage of insulin for dogs. The supplemental NADA is approved as of March 24, 2008, and the regulations are amended in 21 CFR 522.1160 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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.

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.

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 approval qualifies for 3 years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the indication for use in cats for which this supplement is approved.

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. In § 522.1160, revise paragraphs (a) and (c) to read as follows:

§ 522.1160 Insulin.

(a) *Specifications*. Each milliliter of porcine insulin zinc suspension contains 40 international units (IU) of insulin.

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer an initial once-daily dose of 0.5 IU per kilogram of body weight by subcutaneous injection concurrently with or right after a meal. Adjust this once-daily dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(ii) *Indications for use*. For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. Administer an initial dose of 1 to 2 IU by subcutaneous