The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 97

Air traffic control, Airports, Navigation (air).

Issued in Washington, DC, on January 22, 1999.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25, LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective February 25, 1999*

Victorville, CA, Southern California Intl, VOR/DME RWY 17, Orig
Newton, IA, Newton Muni, GPS RWY 14 Orig
Newton, IA, Newton Muni, GPS RWY 32, Orig
East Hampton, NY, East Hampton, VOR OR GPS–A, Amdt 10
East Hampton, NY, East Hampton, VOR/DME RNAV OR GPS RWY 10, Amdt 6
East Hampton, NY, East Hampton, VOR/DME RNAV OR GPS RWY 28, Amdt 3
Fulton, NY, Oswego County, VOR OR GPS RWY 33, Amdt 4
Philadelphia, PA, Philadelphia Intl. VOR/DME RNAV OR GPS RWY 17, Amdt 4, CANCELLED

** * * Effective March 25, 1999*

Cold Bay, AK, Cold Bay, VOR RWY 14, Amdt 13
Cold Bay, AK, Cold Bay, VOR/DME OR TACAN OR GPS–A, Amdt 1
Cold Bay, AK, Cold Bay, LOC/DME BC RWY 32, Amdt 7
Cold Bay, AK, Cold Bay, NDB RWY 14, Amdt 11
Cold Bay, AK, Cold Bay, ILS RWY 14, Amdt 16
Cold Bay, AK, Cold Bay, MLS RWY 32, Orig
Cold Bay, AK, Cold Bay, GPS RWY 14, Orig
Cold Bay, AK, Cold Bay, GPS RWY 32, Orig
Carlsbad, CA, McClellan-Palomar, VOR OR GPS–A, Amdt 7
El Monte, CA, El Monte, VOR OR GPS–A, Amdt 7
El Monte, CA, El Monte, VOR/DME OR, GPS–B, Amdt 3
El Monte, CA, El Monte, NDB OR GPS–C, Amdt 1
Los Angeles, CA, Los Angeles Intl, ILS RWY 25R, Amdt 13
Modesto, CA, Modesto City-County-Harry Sham Field, VOR/DME RWY 28R, Orig
Modesto, CA, Modesto City-County-Harry Sham Field, VOR RWY 28R, Amdt 11
Modesto, CA, Modesto City-County-Harry Sham Field, NDG RWY 28R, Amdt 8
Modesto, CA, Modesto City-County-Harry Sham Field, ILS RWY 28R, Amdt 13
Stockton, CA, Stockton Metropolitan, GPS RWY 29R, Orig
Guthrie Center, IA, Guthrie County Regional, NDB RWY 18, Orig
Guthrie Center, IA, Guthrie County Regional, GPS RWY 36, Orig
Concordia, KS, Blosser Muni, NDB–A, Orig
Concordia, KS, Blosser Muni, NDB OR GPS RWY 17, Amdt 1A, CANCELLED
Concordia, KS, Blosser Muni, GPS RWY 17, Orig
Concordia, KS, Blosser Muni, GPS RWY 35, Orig
St. Paul, MN, ST. Paul Downtown Holman Field, ILS RWY 32, Amdt 4
Linden, NJ, Linden, VOR OR GPS–C, Orig-B, CANCELLED
Linden, NJ, Linden, VOR/DME OR GPS–D, Orig-B, CANCELLED
Linden, NJ, Linden, GPS–A, Orig
Malone, NY, Malone-Dufort, VOR/DME–A, Amdt 1
Malone, NY, Malone-Dufort, GPS RWY 5, Orig
Malone, NY, Malone-Dufort, GPS RWY 23, Orig
Roxboro, NC, Person County, LOC RWY 6, Amdt 2, CANCELLED
Roxboro, NC, Person County, NDB OR GPS RWY 6, Amdt 3
Roxboro, NC, Person County, ILS RWY 6, Orig
Roxboro, NC, Person County, GPS RWY 6, Orig
Wilmington, NC, Wilmington Intl, LOC BC RWY 17, Amdt 7
Fargo, ND, Hector Intl, VOR/DME RNAV OR GPS RWY 13, Amdt 6, CANCELLED
Carlisle, PA, Carlisle, VOR/DME OR GPS–A, Amdt 1A, CANCELLED
Carlisle, PA, Carlisle, NDB OR GPS RWY 28, Amdt 2A, CANCELLED
Carlisle, PA, Carlisle, VOR–A, Orig
Carlisle, PA, Carlisle, NDB–B, Orig
Chester, SC, Chester, SC, GPS RWY 17, Orig
Chester, SC, Chester, SC, GPS RWY 35, Orig
North Myrtle Beach, SC, Grand Strand, GPS RWY 5, Orig
North Myrtle Beach, SC, Grand Strand, GPS RWY 23, Orig
San Angelo, TX, Mathis Field, LOC BC RWY 21, Amdt 14
San Angelo, TX, Mathis Field, NDB RWY 3, Amdt 14
San Angelo, TX, Mathis Field, VOR RWY 21, Amdt 16
San Angelo, TX, Mathis Field, ILS RWY 3, Amdt 21
San Angelo, TX, Mathis Field, RADAR–1, Amdt 1
San Angelo, TX, Mathis Field, GPS RWY 3, Orig
San Angelo, TX, Mathis Field, GPS RWY 21, Orig
Seattle, WA, Boeing Field/King Country Intl, LOC CB RWY 31L, Amdt 10, CANCELLED

[FR Doc, 99–2657 Filed 2–3–99; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; 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 supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for subcutaneous use of florfenicol injectable solution for control of respiratory disease in cattle at high risk of developing bovine respiratory disease (BRD).

EFFECTIVE DATE: February 4, 1999.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7570.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 1982, Union, NJ

07083–1982, is sponsor of NADA 141–063 that provides for veterinary prescription use of Nuflor® Injectable Solution (florfenicol) for treatment of cattle for BRD. The firm filed a supplemental NADA that provides for veterinary prescription use of Nuflor® Injectable Solution (florfenicol) by a single subcutaneous injection for control of respiratory disease in cattle at high risk of developing BRD associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus*. The supplemental NADA is approved as of December 17, 1998, and the regulations are amended by revising 21 CFR 522.955(d)(1) 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 supplement 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 supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning December 17, 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 approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to subcutaneous use of the drug for control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*, *P. multocida*, and *H. somnus*.

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 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 paragraph (d)(1)(i), by redesignating paragraph (d)(1)(ii) as paragraph (d)(1)(i)(B), and by adding paragraphs (d)(1)(ii)(A) and (d)(1)(ii)(B) to read as follows:

§ 522.955 Florfenicol solution.

* * * * *

(d) * * *

(1) * * *

(i) *Treatment of disease*—(A) *Amount.* 20 milligrams per kilogram of body weight (3 milliliters per 100 pounds) as an intramuscular injection. A second dose should be given 48 hours later. Alternatively, 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) as a single subcutaneous injection may be used.

(B) *Indications for use.* * * *

(ii) *Control of disease*—(A) *Amount.* 40 milligrams per kilogram of body weight (6 milliliters per 100 pounds) as a single subcutaneous injection.

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

* * * * *

Dated: January 13, 1999.

Andrew J. Beaulieu,

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

[FR Doc. 99–2686 Filed 2–3–99; 8:45 am]

BILLING CODE 4160–01–F

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 Roxarsone With Monensin

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 Alpharma Inc. The supplemental NADA provides for using approved single ingredient bacitracin methylene disalicylate (BMD), monensin, and roxarsone Type A medicated articles to make an additional use level of BMD in Type C medicated broiler chicken feeds.

EFFECTIVE DATE: February 4, 1999.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 116–088 that provides for combining approved BMD® (10, 25, 30, 50, 60, or 75 grams per pound (g/lb) BMD), Coban® (45 or 60 g/lb monensin sodium), and 3–Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds containing 100 to 200 g/ton(t) BMD, 90 to 110 g/t monensin sodium, and 22.7 to 45.4 g/t roxarsone. The BMD, monensin, and 22.7 to 34 g/t roxarsone Type C medicated feeds are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency. The BMD, monensin, and 22.7 to 45.4 g/t roxarsone Type C medicated feeds are used as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD; as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain. The supplemental NADA is approved as of December 24, 1998, and the regulations are amended in 21 CFR 558.355 by revising paragraph (b)(11) and adding paragraphs (f)(1)(xxvi) and (f)(1)(xxvii) to reflect the approval. The basis for 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 the 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.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a