(b) *Sponsors.* See 012579 in § 510.600(c) of this chapter for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section. See 021641 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) 120 milligrams trenbolone acetate and 24 milligrams estradiol in 6 pellets with 29 milligrams tylosin tartrate as a local antibacterial in 1 pellet per implant dose.

* * * * *

Dated: August 24, 1999.

Claire M. Lathers,

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

[FR Doc. 99–22995 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Enrofloxacin Tablets

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 Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for an additional tablet size for enrofloxacin tablets used in dogs and cats for the management of diseases associated with bacteria susceptible to enrofloxacin and for the removal of a tablet size no longer marketed.

EFFECTIVE DATE: September 3, 1999.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1705.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140–441 Baytril® tablets (enrofloxacin) that provides for 136-milligram (mg) tablet size in addition to 22.7- and 68.0-mg tablets. Furthermore, the sponsor stated that the 5.7-mg tablets are no longer marketed and has requested the size be deleted. The supplemental NADA is approved as of August 3, 1999, and the regulations are amended in 21 CFR 520.812(a) to reflect the approval.

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.

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.

§ 520.812 [Amended]

2. Section 520.812 *Enrofloxacin tablets* is amended in paragraph (a) by removing ''5.7, 22.7, or 68.0'' and adding in its place ''22.7, 68.0, or 136.0'' .

Dated: August 24, 1999.

Claire M. Lathers,

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

[FR Doc. 99–22998 Filed 9–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs For Use In Animal Feeds; Semduramicin and Virginiamycin

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 Pfizer, Inc. The NADA provides for using approved single ingredient semduramicin and virginiamycin Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. Approval of the NADA also provides for tolerances for semduramicin residues and an acceptable daily intake (ADI) for semduramicin and for virginiamycin.

EFFECTIVE DATE: September 3, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–114 that provides for combining approved Aviax® (22.7 grams per pound (g/lb) semduramicin) and Stafac® (20 or 227 g/lb virginiamycin) Type A medicated articles to make combination drug Type C medicated broiler chicken feeds. The Type C medicated broiler feeds containing 25 parts per million (ppm) (22.7 g/ton (t)) semduramicin and 5 to 15 g/t virginiamycin are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain. The Type C medicated broiler feeds containing 25 ppm semduramicin and 5 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for increased rate of weight gain and improved feed efficiency. The Type C medicated broiler feeds containing 25 ppm semduramicin and 20 g/t virginiamycin are used for the prevention of coccidiosis caused by *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, *E. necatrix*, and *E. mivati/mitis*, and for prevention of necrotic enteritis caused by *Clostridium*

perfringens susceptible to virginiamycin.

The NADA is approved as of July 27, 1999. The regulations are amended in 21 CFR 558.555 by redesignating paragraph (b) as paragraph (d), by adding new paragraph (b) and adding and reserving paragraph (c), by revising the heading of newly redesignated paragraph (d), by removing the introductory text of newly redesignated paragraph (d)(1), and by adding paragraphs (d)(5), (d)(6), and (d)(7) to reflect the approval. Also, the regulations are amended in 21 CFR 558.635 by removing paragraphs (a), (c), (e)(3), and (e)(4), by redesignating paragraphs (b), (d), (e), and (f) as paragraphs (a), (b), (c), and (d), by correcting the cross-references in newly redesignated paragraph (a) from paragraph (f) to paragraph (d), by correcting a typographical error in newly redesignated paragraph (d)(2)(i), and by adding paragraph (d)(4)(vii) to also reflect the approval. The basis for approval is discussed in the freedom of information summary.

Furthermore, neither an ADI for semduramicin or for virginiamycin nor a tolerance for semduramicin residues have been previously established. At this time, 21 CFR 556.597 is added to establish an ADI and a tolerance for semduramicin. Also, 21 CFR 556.750 is amended to remove language referring to negligible residues in swine, broiler chicken, and cattle tissues to provide for an ADI for virginiamycin, and to reflect a revised 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.

The agency has determined under 21 CFR 25.33(a)(2) 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

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

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

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

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

2. Section 556.597 is added to read as follows:

§ 556.597 Semduramicin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of semduramicin is 180 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Broiler chickens.* Tolerances are established for residues of parent semduramicin in uncooked edible tissues of 400 parts per billion (ppb) in liver and 130 ppb in muscle.

(2) [Reserved]

3. Section 556.750 is revised to read as follows:

§ 556.750 Virginiamycin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of virginiamycin is 250 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Swine.* Tolerances are established for residues of virginiamycin in uncooked edible tissues of 0.4 part per million (ppm) in kidney, skin, and fat, 0.3 ppm in liver, and 0.1 ppm in muscle.

(2) *Broiler chickens and cattle.* A tolerance for residues of virginiamycin is not required.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

4. The authority citation for 21 CFR part 558 continues to read as follows:

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

5. Section 558.555 is amended by redesignating paragraph (b) as paragraph (d), by adding new paragraph (b) and adding and reserving paragraph (c), by revising the heading of newly redesignated paragraph (d), by removing the introductory text of newly redesignated paragraph (d)(1), and by adding paragraphs (d)(5), (d)(6), and (d)(7) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(b) *Related tolerances.* See § 556.597 of this chapter.

(c) [Reserved]

(d) *Conditions of use in broiler chickens.* * * *

(5) *Amount.* Semduramicin 22.7 grams with virginiamycin 20 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/mitis,* and for prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

(6) *Amount.* Semduramicin 22.7 grams with virginiamycin 5 to 15 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/mitis,* and for increased rate of weight gain.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

(7) *Amount.* Semduramicin 22.7 grams with virginiamycin 5 grams per ton.

(i) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. mivati/mitis,* and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Semduramicin and virginiamycin as provided by 000069 in § 510.600(c) of this chapter.

6. Section 558.635 is amended by removing paragraphs (a), (c), (e)(3), and (e)(4), by redesignating paragraphs (b), (d), (e), and (f) as paragraphs (a), (b), (c), and (d), respectively, by removing ''(f)'' and ''(f)(3)'' in newly redesignated paragraph (a)(1) and adding in their places ''(d)'' and ''(d)(3)'', by removing ''(f)(1)(iv)'' and ''(f)(1)(v)'' in newly redesignated paragraph (a)(2) and adding in their places ''(d)(1)(iv)'' and ''(d)(1)(v)'', by removing ''chiickens'' in newly redesignated paragraph (d)(2)(i) and adding in its place ''chickens'', and

by adding paragraph (d)(4)(vii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(d) * * *

(4) * * *

(vii) Semduramicin as in § 558.555 of this chapter.

Dated: August 24, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–22997 Filed 9–3–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA–19–01–5892a; A–1–FRL–6421–8]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Volatile Organic Compound Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Massachusetts. This revision establishes reasonably available control technology (RACT) emission limits for certain industrial categories. The intended effect of this action is to fully approve the majority of the Commonwealth's SIP revision submitted on November 13, 1992 and February 17, 1993. The EPA is granting approval to the generic RACT rule in Title 310 Code of Massachusetts Regulations (CMR) section 7.18(17) only in the Springfield, Massachusetts ozone nonattainment area (Berkshire, Franklin, Hampden and Hampshire counties). EPA will address 310 CMR 7.18(17) as it applies to the Boston, Massachusetts ozone nonattainment area in a future action. This action is being taken under section 110 of the Clean Air Act (Act). 42 U.S.C. 7410.

DATES: This rule will become effective November 2, 1999 without further notice, unless EPA receives relevant adverse comments on the parallel notice of proposed rulemaking by October 4, 1999. If EPA receives such comment, then it will publish a document in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection (mail code CAA), U.S. Environmental Protection Agency, Region I, 1 Congress Street, Boston, MA 02114–2023. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office Ecosystem Protection, U.S. Environmental Protection Agency, Region I, One Congress Street, 11th floor, Boston, MA, and at the Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Jeanne Cosgrove, (617) 918–1669.

SUPPLEMENTARY INFORMATION: On November 13, 1992 and February 17, 1993, the Massachusetts Department of Environmental Protection (DEP) submitted a revision to its SIP. The revision consisted of changes and additions made to Massachusetts' volatile organic compound (VOC) rules pursuant to the requirements of section 182(b)(2) of the Act, 42 U.S.C. 7511a(b)(2). Changes were made to the following regulations: 310 CMR 7.00, Definitions; 310 CMR 7.03(13), Paint spray booths; 310 CMR 7.18(2), Compliance with emission limitations; 310 CMR 7.18(7), Automobile surface coating; 310 CMR 7.18(8), Solvent Metal Degreasing; 310 CMR 7.18(11), Surface coating of miscellaneous metal parts and products; 310 CMR 7.18(12), Graphic arts; 310 CMR 7.18(17), Reasonably available control technology; and 310 CMR 7.24(3), Distribution of motor vehicle fuel. Additionally, the following new rules were added to Massachusetts' Code: 310 CMR 7.18(20), Emission control plans for implementation of reasonably available control technology; 310 CMR 7.18(21), Surface coating of plastic parts; 310 CMR 7.18(22), Leather surface coating; 310 CMR 7.18(23), Wood products surface coating; 310 CMR 7.18(24), Flat wood paneling surface coating; 310 CMR 7.18(25), Offset lithographic printing; 310 CMR 7.18(26), Textile finishing; and 310 CMR 7.18(27), Coating mixing tanks.

I. Background

Under the pre-amended Clean Air Act, ozone nonattainment areas were required to adopt RACT rules for sources of VOC emissions. EPA issued three sets of control technique guidelines (CTGs) documents, establishing a ''presumptive norm'' for RACT for various categories of VOC sources. The three sets of CTGs were (1) Group I—issued before January 1978 (15 CTGs); (2) Group II—issued in 1978 (9 CTGs); and (3) Group III—issued in the early 1980's (5 CTGs). Those sources not covered by a CTG were called non-CTG sources. EPA determined that the area's SIP-approved attainment date established which RACT rules the area needed to adopt and implement. Under section 172(a)(1), ozone nonattainment areas were generally required to attain the ozone standard by December 31, 1982. Those areas that submitted an attainment demonstration projecting attainment by that date were required to adopt RACT for sources covered by the Group I and II CTGs. Those areas that sought an extension of the attainment date under section 172(a)(2) to as late as December 31, 1987 were required to adopt RACT for all CTG sources and for all major (i.e., 100 ton per year or more of VOC emissions) non-CTG sources.

Under the pre-amended Act, Massachusetts was designated as nonattainment for ozone and sought an extension of the attainment date under section 172(a)(2) to December 31, 1987. Therefore, the Commonwealth was required to adopt RACT for all CTG sources and for all major (i.e., 100 ton per year or more of VOC emissions) non-CTG sources. However, the Commonwealth of Massachusetts did not attain the ozone standard by the approved attainment date. On May 25, 1988, EPA notified the Governor of Massachusetts that portions of the SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, amendments to the 1977 CAA were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that pre-enactment ozone nonattainment areas that retained their designation of nonattainment and were classified as marginal or above fix their deficient RACT rules for ozone by May 15, 1991. The entire Commonwealth of Massachusetts retained its designation of nonattainment and was classified as serious nonattainment for ozone. 56 FR 56694 (Nov. 6, 1991). The Commonwealth submitted revisions to meet the RACT fix-up requirement and EPA has approved those revisions to the Massachusetts SIP on October 8, 1992, January 11, 1993 and June 30, 1993 (57 FR 46313, 58 FR 3492 and 58 FR 34908.)

Section 182(b)(2) of the amended Act requires States to adopt RACT rules for all areas designated nonattainment for ozone and classified as moderate or above. There are three parts to the section 182(b)(2) RACT requirement: (1) RACT for sources covered by an existing CTG—i.e., a CTG issued prior to the enactment of the Clean Air Act Amendments of 1990; (2) RACT for