SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed supplemental NADA 140–338, which provides for use of Naxcel® Sterile Powder (ceftiofur sodium) in sheep as a 50 milligrams per milliliter reconstituted injectable solution. The product is currently approved for use in cattle, swine, day-old chicks, horses, and dogs. The supplemental NADA is approved as of October 25, 1996, and the regulations are amended in 21 CFR 522.313 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the regulations are amended in 21 CFR 556.113 to state that a tolerance for ceftiofur residues in edible tissues of sheep is not required.

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, 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval does not qualify for marketing exclusivity because it does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety or human food safety (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 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, Food.

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. Section 522.313 is amended by adding new paragraph (d)(7) to read as follows:

§ 522.313 Ceftiofur sterile powder for injection.

* * * * *

(d) * * *

(7) *Sheep*—(i) *Amount.* 0.5 to 1.0 milligram per pound (1.1 to 2.2 milligrams per kilogram) of body weight.

(ii) *Indications for use.* For treatment of sheep respiratory disease (pneumonia) associated with *Pasteurella haemolytica* and/or *P. multocida.*

(iii) *Limitations.* For intramuscular use only. Treatment should be repeated at 24 hour intervals for a total of 3 consecutive days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response. Use of dosages in excess of those indicated or by unapproved routes of administration may result in illegal residues in tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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).

§ 556.113 [Amended]

4. Section 556.113 *Ceftiofur* is amended by removing ''and poultry'' and by adding in its place ''poultry, and sheep''.

Dated: December 6, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32071 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Semduramicin with Bacitracin Methylene Disalicylate

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 Type A medicated articles to make combination drug Type C medicated broiler chicken feeds containing semduramicin with bacitracin methylene disalicylate. The Type C medicated feed is used for prevention of coccidiosis and for improved feed efficiency.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1607.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–065, which provides for combining approved Type A medicated articles containing Aviax™ (semduramicin sodium) with BMD® (bacitracin methylene disalicylate) to make combination drug Type C medicated broiler chicken feed containing 22.7 grams (g) of semduramicin and 10 to 50 g of bacitracin methylene disalicylate. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria acervulina*, *E. brunetti*, *E. maxima*, *E. mivati/E. mitis*, *E. necatrix*, and *E. tenella*, and for improved feed efficiency in broiler chickens. The NADA is approved as of October 18, 1996, and the regulations are amended by revising 21 CFR 558.76(d)(3)(xiv) and by adding 21 CFR 558.555(b)(3) 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 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years marketing exclusivity beginning October 18, 1996, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(ii) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

2. Section 558.76 is amended by revising paragraph (d)(3)(xiv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate

* * * * *

(d) * * *

(3) * * *

(xiv) Semduramicin alone or in combination with roxarsone as in § 558.555.

3. Section 558.555 is amended by adding new paragraph (b)(3) to read as follows:

§ 558.555 Semduramicin.

* * * * *

(b) * * *

(3) *Amount.* Semduramicin 22.7 grams with bacitracin methylene disalicylate 10 to 50 grams per ton.

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

(ii) *Limitations.* Feed continuously as sole ration. Use feed within 2 weeks of production. Do not feed to laying hens. Semduramicin as provided by 000069, bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

Dated: December 6, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32035 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 301, and 602

[TD 8697]

RIN 1545–AT91

Simplification of Entity Classification Rules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that classify certain business organizations under an elective regime. These regulations replace the existing classification rules.

DATES: These regulations are effective as of January 1, 1997.

For dates of applicability of these regulations, see Effective Dates under Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Mark D. Harris, (202) 622–3050; concerning foreign organizations, William H. Morris or Ronald M. Gootzeit, (202) 622–3880 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in these final regulations have been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545–1486. Responses to these collections of information are required to obtain a benefit (to choose an entity's classification by election).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimates of the reporting burden in these final regulations are reflected in the burden estimates in Form 8832 (Entity Classification Election).

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Books or records relating to these collections of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background

On April 3, 1995, Notice 95–14 (1995–1 C.B. 297), relating to classification of business organizations under section 7701 of the Code, was published in the Internal Revenue Bulletin. A notice of public hearing was published in the Federal Register on May 10, 1995 (60 FR 24813). Written comments were received and a public hearing was held on July 20, 1995.

On May 13, 1996, the IRS and Treasury issued a notice of proposed rulemaking (61 FR 21989 [PS–43–95, 1996–24 I.R.B. 20]) under section 7701. The regulations proposed to replace the existing regulations for classifying certain business organizations with an elective regime. Comments responding to the notice were received, and a public hearing was held on August 21, 1996. After considering the comments that were received in response to the notice of proposed rulemaking and the statements made at the public hearing, the proposed regulations are adopted as revised by this Treasury decision. The revisions are discussed below.

Explanation of Provisions

Section 7701(a)(2) of the Code defines a partnership to include a syndicate, group, pool, joint venture, or other unincorporated organization, through or by means of which any business, financial operation, or venture is carried on, and that is not a trust or estate or a corporation. Section 7701(a)(3) defines a corporation to include associations, joint-stock companies, and insurance companies.

The existing regulations for classifying business organizations as associations (which are taxable as corporations under section 7701(a)(3)) or as partnerships under section 7701(a)(2) are based on the historical differences under local law between partnerships and corporations. Treasury and the IRS believe that those rules have become increasingly formalistic. This document replaces those rules with a much simpler approach that generally is elective.