

Acrylic copolymers (CAS Reg. No. 30394-86-6): Prepared by reaction of ethyl acrylate (CAS Reg. No. 140-88-5), methyl methacrylate (CAS Reg. No. 80-62-6), and methacrylamide (CAS Reg. No. 79-39-0) blended with melamine-formaldehyde resin (CAS Reg. No. 68002-20-0). For use in coatings for polyethylene phthalate films complying with paragraph (a) of this section.

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Dated: August 23, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-22695 Filed 9-4-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfadimethoxine/Ormetoprim 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 Pfizer, Inc. The approved NADA provides for oral use of sulfadimethoxine/ormetoprim tablets in dogs for the treatment of certain bacterial skin and soft tissue infections (wounds and abscesses). The supplement adds the treatment of certain bacterial urinary tract infections. This product is limited to veterinary prescription use.

EFFECTIVE DATE: September 5, 1996

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1617.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 100-929, which provides for oral use of Primor® (sulfadimethoxine/ormetoprim) tablets in dogs for the treatment of urinary tract infections caused by *Escherichia coli*, *Staphylococcus* spp., and *Proteus mirabilis* susceptible to the combination of sulfadimethoxine/ormetoprim in addition to its approved use for skin and soft tissue infections (wounds and abscesses) caused by strains of *S. aureus* and *E. coli* susceptible to sulfadimethoxine/ormetoprim. This product is limited to use by or on the order of a licensed veterinarian. The supplement is approved as of August 5, 1996, and the regulations are amended in 21 CFR 520.2220d 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 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 supplemental approval qualifies for 3 years of marketing exclusivity beginning August 5, 1996, because the supplement contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to use in treating urinary tract infections.

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

§ 520.2220d [Amended]

2. Section 520.2220d *Sulfadimethoxine-ormetoprim tablets* is amended in paragraph (c)(2) by adding the phrase "and urinary tract infections caused by *Escherichia coli*, *Staphylococcus* spp., and *Proteus mirabilis*" after "*Escherichia coli*".

Dated: August 23, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-22694 Filed 9-4-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8029]

Furnishing Statements Required With Respect to Certain Substitute Payments; Correction

AGENCY: Internal Revenue Services (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains a correction to final regulations (TD 8029), which were published in the Federal Register on Wednesday, June 5, 1985 (50 FR 23676) relating to statements required to be furnished by brokers and information returns of brokers.

EFFECTIVE DATE: June 5, 1985.

FOR FURTHER INFORMATION CONTACT: Donna Welch, (202) 622-4910, (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under sections 6042, 6045 and 6049 of the Internal Revenue Code.

Need for Correction

The final regulations (TD 8029) omitted instructions to remove § 1.6045-2T and the entry for the OMB control number. It is the intent of this document to make these removals as of the publication of the final regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Correcting Amendment to Regulations

Accordingly, 26 CFR parts 1 and 602 are corrected by making the following correcting amendments:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows: