Pl., Rockville, MD 20855, 301–827–0159; e-mail: *msharar@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 119–807 for BEUTHANASIA–D–SPECIAL Solution and Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113, filed a supplement to ANADA 200–071 for EUTHASOL Solution. The supplemental applications provide for the addition of environmental warning statements to product labeling. The supplemental applications are approved as of May 2, 2003, and the regulations are amended in § 522.900 (21 CFR 522.900) to reflect the approvals.

In addition, the agency has found that the regulations do not reflect the 1996 change of sponsorship (61 FR 5505, February 13, 1996) of NADA 128–967 for REPOSE Euthanasia Solution from Syntex Animal Health, Division of Syntex Agri-business, Inc., to Fort Dodge Animal Health, Division of Wyeth. At this time, § 522.900 is revised to reflect that change of sponsorship and a current format.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are 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 the 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 522.900 is revised to read as follows:

§ 522.900 Euthanasia solution.

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

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061 and 059079 for use of product described in paragraph (a)(1) of this section.

(2) No. 000856 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations.* Product labeling shall bear the following warning statements:

''ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.''

(d) *Conditions of use in dogs*—(1) *Indications for use.* For humane, painless, and rapid euthanasia.

(2) *Amount.* One mL per 10 pounds of body weight.

(3) *Limitations.* Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 7, 2003.

Clifford Johnson,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 03–18352 Filed 7–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Gentamicin Sulfate, Betamethasone Valerate, Clotrimazole Ointment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of gentamicin sulfate, betamethasone valerate, and clotrimazole ointment for the treatment of canine otitis externa.

DATES: This rule is effective July 21, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–287 that provides for use of gentamicin sulfate, United States Pharmacopeia (USP); betamethasone valerate, USP; and clotrimazole, USP; (GBC) Ointment for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin. Phoenix Scientific's GBC Ointment is approved as a generic copy of Schering-Plough Animal Health's OTOMAX Ointment approved under NADA 140–896. The ANADA is approved as of March 28, 2003, and the regulations are amended in § 524.1044g (21 CFR 524.1044g) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 524.1044g is being amended to reflect the supplemental approval of several additional container sizes under NADA 140–896 and ANADA 200–229, which were not codified, and to reflect a current format.

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(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 524

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 524 is amended as follows:

PART 524–OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 2. Section 524.1044g is amended by revising paragraphs (b) and (c) to read as follows:

§ 524.1044g Gentamicin sulfate, betamethasone valerate, clotrimazole ointment.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(1) No. 000061 for use of 7.5- or 15-gram (g) tubes, 12.5-, 30-, or 215-g bottles.

(2) No. 051259 for use of 7.5- or 15-g tubes, 10-, or 25-g bottles.

(3) No. 059130 for use of 10- or 215-g bottles.

(c) *Conditions of use in dogs*—(1) *Amount.* Instill ointment twice daily into the ear canal. Therapy should continue for 7 consecutive days.

(i) From 7.5- or 15-g tubes, 10-, 12.5-, 25-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

(ii) From 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

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

Dated: July 3, 2003.

Andrew J. Beaulieu,

Associate Director, Center for Veterinary Medicine.

[FR Doc. 03–18353 Filed 7–18–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9081]

RIN 1545–BC33

Prohibited Allocations of Securities in an S Corporation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations concerning requirements for employee stock ownership plans (ESOPs) holding stock of Subchapter S corporations. The temporary regulations provide guidance on identifying disqualified persons and determining whether a plan year is a nonallocation year under Section 409(p) and on the definition of synthetic equity under section 409(p)(5). These temporary regulations would generally affect plan sponsors of, and participants in, ESOPs holding stock of Subchapter S corporations. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective July 21, 2003.

Applicability Date: These temporary regulations are applicable with respect to plan years ending after October 20, 2003.

FOR FURTHER INFORMATION CONTACT: John T. Ricotta at (202) 622–6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 4975(e)(7) provides that an ESOP is a defined contribution plan that is designed to invest primarily in qualifying employer securities and that is either a stock bonus plan which is qualified, or a stock bonus plan and money purchase pension plan both of which are qualified, under section 401(a). Section 4975(e)(7) authorizes the Secretary to issue regulations imposing additional requirements for ESOPs (*see* § 54.4975–11 of the Excise Tax Regulations). A plan is not treated as an ESOP under the Code unless it meets the following requirements, to the extent applicable: Section 409(h) (relating to participants' right to receive employer securities; put options); section 409(o) (relating to participants' distribution rights and payment requirements); section 409(n) (relating to securities received in transactions to which section 1042 applies); section 409(p) (relating to prohibited allocations of securities in an S corporation); section 664(g) (relating to qualified gratuitous transfers of qualified employer securities); and section 409(e) (relating to participants' voting rights if the employer has a registration-type class of securities). As authorized by section 4975(e)(7), additional requirements are imposed under § 54.4975–11.

Section 1361(b)(1)(D) provides that a Subchapter S corporation (S corporation) may not have more than one class of stock. Section 1361(b)(1)(B) provides that an S corporation may not have as a shareholder a person that is not an estate, a trust described in section 1361(c)(2), an organization described in section 1361(c)(6), or an individual. In 1996, section 1361(c)(6) was amended to permit a qualified plan under section 401(a) to be a shareholder in an S corporation. Section 1316(a) of the Small Business Job Protection Act of 1996 (SBJPA) (110 Stat. 1755) (1996).

Section 511(a)(1) imposes a tax on the unrelated business taxable income (as defined in section 512(a)) of organizations described in section 511(a)(2), which include plans that qualify under section 401(a). Section 512(e)(1) provides that if an organization described in section 1361(c)(6) holds stock in an S corporation, the interest is treated as an interest in an unrelated trade or business and, notwithstanding the organization's general tax-exempt status, all items of income, loss, or deduction taken into account under section 1366(a) and any gain or loss on the disposition of the stock in the S corporation are taken into account in computing the unrelated business taxable income of the organization. In 1997, section 512(e) was amended to provide that section 512(e) does not apply to employer securities (within the meaning of section 409(l)) held by an ESOP described in section 4975(e)(7). Section 1523 of the Taxpayer Relief Act of 1997 (TRA '97) (111 Stat. 788) (1997). Accordingly, S corporation income allocable to stock held by an ESOP is not subject to regular income or unrelated business income tax, but S corporation income allocable to stock held by any other qualified plan or tax-exempt entity under section 501(c)(3) is subject to the unrelated business income tax under section 511.

Congress became aware that the tax exemption for earnings on S corporation stock held by an ESOP may lead to