

Commission certifies that this proposed rule, if finalized, would not have such an impact on small entities.

Document Availability

24. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington DC 20426.

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Effective Date

27. These regulations are effective September 9, 2004. The provisions of 5 U.S.C. 801 regarding Congressional review of Final Rules do not apply to this Final Rule, because the rule concerns agency procedure and practice and will not substantially affect the rights of non-agency parties.

List of Subjects in 18 CFR Part 388

Confidential business information, Freedom of information.

By the Commission.

Magalie R. Salas,
Secretary.

■ In consideration of the foregoing, the Commission amends part 388, Chapter I, Title 18, *Code of Federal Regulations*, as follows:

PART 388—INFORMATION AND REQUESTS

■ 1. The authority citation for part 388 continues to read as follows:

Authority: 5 U.S.C. 301–305, 551, 552 (as amended), 553–557; 42 U.S.C. 7101–7352.

■ 2. In § 388.113, paragraph (d)(1) is revised, paragraph (d)(2) is removed, and (d)(3) is redesignated as (d)(2), to read as follows:

§ 388.113 Accessing critical energy infrastructure information.

* * * * *

(d) *Optional procedures for requesting critical energy infrastructure information.* (1) An owner/operator of a facility, including employees and officers of the owner/operator, may obtain CEII relating to its own facility directly from Commission staff without going through the procedures outlined in paragraph (d)(2) of this section. Non-employee agents of an owner/operator of such facility may obtain CEII relating to the owner/operator's facility in the same manner as owner/operators as long as they present written authorization from the owner/operator to obtain such information.

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[FR Doc. 04–18189 Filed 8–9–04; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Doramectin

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 supplemental NADA provides for an increased period of protection from reinfection with three species of internal parasites following topical administration of doramectin solution on cattle.

DATES: This rule is effective August 10, 2004.

FOR FURTHER INFORMATION CONTACT:

Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: janis.messenheimer@fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–095 for DECTOMAX (doramectin) Pour-On Solution for Cattle. The

supplemental application provides for an increased period of protection from reinfection with three species of internal parasites following topical administration of doramectin solution on cattle. Specifically, the period of persistent effectiveness is increased from 21 days to 28 days for *Cooperia oncophora*, from 28 days to 35 days for *C. punctata*, and from 21 days to 28 days for *Dictyocaulus viviparus*. The supplemental NADA is approved as of June 30, 2004, and the regulations in 21 CFR 524.770 are amended to reflect the approval and a current format. 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 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.

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 qualifies for 3 years of marketing exclusivity beginning June 30, 2004. Exclusivity applies only to the extension of the persistent effectiveness claims for the three species of parasites listed previously.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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 524.770 is revised to read as follows:

§ 524.770 Doramectin.

(a) *Specifications.* Each milliliter (mL) of solution contains 5 milligrams (mg) doramectin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Administer topically as a single dose 0.5 mg (1 mL) per kilogram (1 mL per 22 pounds) body weight.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and fourth-stage larvae), *O. ostertagi* (inhibited fourth-stage larvae), *O. lyrata* (adults), *Haemonchus placei* (adults and fourth-stage larvae), *Trichostrongylus axei* (adults and fourth-stage larvae), *T. colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults and fourth-stage larvae), *C. punctata* (adults and fourth-stage larvae), *C. pectinata* (adults), *C. surnabada* (adults), *Bunostomum phlebotomum* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); eyeworms: *Thelazia gulosa* (adults), *T. skrjabini* (adults); grubs: *Hypoderma bovis* and *H. lineatum*; sucking lice: *Linognathus vituli*, *Haematopinus eurysternus*, and *Solenopotes capillatus*; biting lice: *Damalinia bovis*; mange mites: *Chorioptes bovis* and *Sarcoptes scabiei*; horn flies: *Haematobia irritans*; and to control infections and to protect from reinfection with *C. oncophora*, *D. viviparus*, *O. ostertagi*, and *O. radiatum* for 28 days; and with *C. punctata*, and *H. placei* for 35 days after treatment.

(3) *Limitations.* Do not slaughter cattle within 45 days of latest treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

Dated: July 28, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9148]

RIN 1545-BC06

Transfers of Compensatory Options

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains regulations that provide rules governing transfers of certain compensatory stock options (nonstatutory stock options). The regulations affect persons who have been granted nonstatutory stock options, as well as service recipients who may be entitled to deductions related to the options.

DATES: *Effective Date:* These regulations are effective August 10, 2004.

Applicability Dates: These regulations apply to transfers of nonstatutory stock options on or after July 2, 2003.

FOR FURTHER INFORMATION CONTACT: Stephen Tackney (202) 622-6030 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

These regulations amend 26 CFR part 1. On July 2, 2003, a temporary regulation (TD 9067) relating to transfers of compensatory options was published in the **Federal Register** (68 FR 39453). A notice of proposed rulemaking (REG-116914-03) was published in the **Federal Register** for the same day (68 FR 39498). No public hearing was requested or held. No written or electronic comments responding to the notice of proposed rulemaking were received. The proposed regulations are adopted without change by this Treasury decision, and the corresponding temporary regulations are removed.

Special Analyses

It has been determined that these regulations are not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these regulations were submitted to the Chief

Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these final regulations is Stephen Tackney of the Office of Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the entry for “1.83-7T” and continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.

■ **Par. 2.** § 1.83-7 is amended as follows:

■ 1. Paragraph (a) is amended by adding two sentences at the end.

■ 2. Paragraphs (a)(1) and (a)(2) are added.

■ 3. Paragraph (d) is revised.

The additions read as follows:

§ 1.83-7 Taxation of nonqualified stock options.

(a) * * * The preceding sentence does not apply to a sale or other disposition of the option to a person related to the service provider that occurs on or after July 2, 2003. For this purpose, a person is related to the service provider if—

(1) The person and the service provider bear a relationship to each other that is specified in section 267(b) or 707(b)(1), subject to the modifications that the language “20 percent” is used instead of “50 percent” each place it appears in sections 267(b) and 707(b)(1), and section 267(c)(4) is applied as if the family of an individual includes the spouse of any member of the family; or

(2) The person and the service provider are engaged in trades or businesses under common control (within the meaning of section 52(a) and (b)); provided that a person is not related to the service provider if the person is the service recipient with respect to the option or the grantor of the option.

* * * * *

(d) This section applies on and after July 2, 2003. For transactions prior to