

Authority: Sec. 6, 38 Stat. 721; 15 U.S.C. 46.

2. Section 4.11 is amended by adding a sentence at the end of paragraphs (c) and (d) and revising paragraph (e) to read as follows:

§ 4.11 Disclosure requests.

* * * * *

(c) * * * Requests for material pursuant to compulsory process, or for voluntary testimony, in cases or matters in which the Commission is not a party will be treated in accordance with paragraph (e) of this section.

(d) * * * Request for material pursuant to compulsory process, or for voluntary testimony, in cases or matters in which the Commission is not a party will be treated in accordance with paragraph (e) of this section.

(e) *Requests for testimony, pursuant to compulsory process or otherwise, and requests for material pursuant to compulsory process, in cases or matters to which the Commission is not a party.*

(1) The procedures specified in this section will apply to compulsory process and requests for voluntary testimony directed to Commission employees, except special government employees, that relate in any way to the employees' official duties. These procedures will also apply to compulsory process and requests for voluntary testimony directed to former Commission employees or to current or former special government employees of the Commission that seek nonpublic materials or information acquired during Commission employment. The provisions of paragraph (e)(3) of this section will also apply when requests described above are directed to the Commission. For purposes of this section, the term *testimony* includes any written or oral statement by a witness, such as depositions, affidavits, declarations, and statements at a hearing or trial; the term *nonpublic* includes any material or information which, under § 4.10, is not required to be more public; the term *employees*, except where otherwise specified, includes *special government employees* and other Commission employees; and the term *special government employees* includes consultants and other employees as defined by section 202 of title 18 of the United States Code.

(2) Any employee or former employee who is served with compulsory process shall promptly advise the General Counsel of its service, the nature of the material or information sought, and all relevant facts and circumstances. This notification requirement also applies to any employee or former employee

whose testimony is sought on a voluntary basis under the conditions set forth in paragraph (e)(1) of this section.

(3) A party who causes compulsory process to be issued to, or who requests testimony by, the Commission or any employee or former employee of the Commission shall furnish a statement to the General Counsel, unless, with respect to a request by a Federal or State agency, the General Counsel determines, as a matter of discretion, to waive this requirement. The statement shall set forth the party's interest in the case or matter, the relevance of the desired testimony or material, and a discussion of whether it is reasonably available from other sources. If testimony is desired, the statement shall also contain a general summary of the testimony and a discussion of whether Commission records could be produced and used in its place. Any authorization for testimony will be limited to the scope of the demand as summarized in such statement.

(4) Absent authorization from the General Counsel, the employee or former employee shall respectfully decline to produce requested material or to disclose requested information. The refusal should be based on this paragraph and on *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

(5) The General Counsel will consider and act upon compulsory process and requests for voluntary testimony under this section with due regard for statutory restrictions, the Commission's rules and the public interest, taking into account such factors as the need to conserve the time of employees for conducting official business; the need to avoid spending the time and money of the United States for private purposes; the need to maintain impartiality between private litigants in cases where a substantial government interest is not involved; and the established legal standards for determining whether justification exists for the disclosure of confidential information and material.

(6) Invitations to testify before Congressional committees or subcommittees or to testify before other government bodies on the possible effects of legislative and regulatory proposals are not subject to paragraphs (e)(1) through (5) of this section.

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By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 99-15187 Filed 6-15-99; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen

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 veterinary prescription use of carprofen chewable tablets for the relief of pain and inflammation associated with osteoarthritis in dogs.

EFFECTIVE DATE: June 16, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed NADA 141-111 that provides for oral veterinary prescription use of Rimadyl® (carprofen) chewable tablets for the relief of pain and inflammation associated with osteoarthritis in dogs. The NADA is approved as of May 14, 1999. The regulations are amended in 21 CFR 520.309 by revising the section heading, by revising paragraph (a), by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraphs (d)(1) and (d)(2) to reflect the approval.

The regulations currently provide for use of carprofen caplets in NADA 141-053. A revision of the indications for use has been approved by letter of April 21, 1999. At this time, the regulation is amended to reflect that 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.

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 for nonfood-producing animals qualifies for 3 years of marketing

exclusivity beginning May 14, 1999, because the application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant. Three years of marketing exclusivity applies only to use of carprofen chewable tablets for relief of pain and inflammation associated with osteoarthritis in dogs.

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 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.

2. Section 520.309 is amended by revising the section heading, by revising paragraph (a), by redesignating paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraphs (d)(1) and (d)(2) to read as follows:

§ 520.309 Carprofen.

(a) *Specifications.* Each caplet or chewable tablet contains 25, 75, or 100 milligrams of carprofen.

* * * * *

(c) [Reserved]

(d) * * *

(1) *Amount.* 1 milligram per pound of body weight twice daily. Caplets and chewable tablets are scored and dosage should be calculated and given in half-caplet or half-chewable tablet increments.

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis in dogs.

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Dated: June 4, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99-15291 Filed 6-15-99; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8805]

RIN 1545-AQ43

Application of Section 904 to Income Subject to Separate Limitations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations that were published in the **Federal Register** on Monday, January 11, 1999 (64 FR 1505) relating to the application of section 904 with respect to certain categories of income.

DATES: This correction is effective March 12, 1999.

FOR FURTHER INFORMATION CONTACT: Rebecca Rosenberg (202) 622-3850 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under section 904 of the Internal Revenue Code.

Need for correction

As published, the final regulations contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR Part 1 is corrected by making the following correcting amendment:

PART 1—INCOME TAXES

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

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

§ 1.904-4 [Corrected]

Par. 2. Section 1.904-4 is amended as follows:

1. Paragraph (c)(1) is amended by adding the sentence "This paragraph (c)(1) is applicable for taxable years beginning after March 12, 1999." at the end of the paragraph.

2. Paragraph (c)(2)(i)(A) is amended by removing the last sentence of the paragraph and adding a new sentence "Paragraph (c)(2)(ii) of this section is applicable for taxable years beginning after March 12, 1999." in its place.

Cynthia E. Grigsby,

Chief, Regulation Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 99-15113 Filed 6-15-99; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-99-056]

RIN 2115-AA97

Safety Zone: Heritage of Price Fireworks, Hudson River, New York

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Heritage of Pride Fireworks Display located on the Hudson River, New York. This zone is necessary to provide for the safety of life on navigable waters during the event. It is intended to restrict vessel traffic in a portion of the Hudson River.

DATES: This temporary final rule is effective from 9:30 p.m. until 11 p.m., on Sunday, June 27, 1999. There is no rain date for this event.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at Coast Guard Activities New York, 212 Coast Guard Drive, room 205, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (718) 354-4193.

FOR FURTHER INFORMATION CONTACT: Lieutenant J. Lopez, Waterways Oversight Branch, Coast Guard Activities New York (718) 354-4193.

SUPPLEMENTARY INFORMATION:

Regulatory History

Pursuant to 5 U.S.C. 553, no notice of proposed rulemaking (NPRM) was published for this temporary final rule. Because of the date the Application for Approval of Marine Event was received, there was insufficient time to draft and publish an NPRM and publish the rule