Dated: December 2, 1998.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98–32741 Filed 12–9–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522, 524, and 556

Animal Drugs, Feeds, and Related Products; 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 two supplemental new animal drug applications (NADA's) filed by Pfizer, Inc. The supplemental NADA's provide for added use of doramectin in cattle for injectable use for additional persistent efficacy for treatment and control of certain gastrointestinal roundworms and lungworms and for topical use for treatment and control of horn flies.

EFFECTIVE DATE: December 10, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 141–061 that provides for subcutaneous and intramuscular use of Dectomax® (doramectin) 1 percent injectable solution in cattle to control infections and to protect from reinfection with *Cooperia oncophora* for 14 days and *Oesophagostomum radiatum* for 28 days after treatment. The new persistent use is in addition to the currently approved use in cattle for treatment and control of various gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites, and to control infections and to protect from reinfection with *Ostertagia ostertagi* for 21 days and *C. punctata* and *Dictyocaulus viviparus* for 28 days after treatment.

Pfizer, Inc., also filed supplemental NADA 141–095 that provides for topical use of Dectomax® (doramectin) 0.5 percent pour-on in beef and nonlactating dairy cattle to treat and control horn flies (*Haematobia irritans*) in addition to its use for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfection with *C. oncophora* and *Dictyocaulus viviparus* for 21 days, and *O. ostertagi, C. punctata,* and *O. radiatum* for 28 days after treatment.

The supplemental NADA's are approved as of October 25, 1998, and the regulations are amended in 21 CFR 522.770(d)(1)(ii) and 524.770(d)(2) to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In addition, a tolerance for doramectin and its residues in cattle muscle has not been previously established. Also, the acceptable daily intake (ADI) for doramectin has not been previously codified. At this time, the regulations are amended in 21 CFR 556.225 to provide for a tolerance for doramectin residues in cattle muscle and an ADI.

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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these supplemental approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning October 25, 1998, because the supplements contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental applications and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin injection to control infections and to protect cattle from reinfection with *C. oncophora* for 14 days and *O. radiatum* for 28 days after treatment, and for doramectin topical for the treatment and control of horn flies (*H. irritans*).

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.

List of Subjects

21 CFR Parts 522 and 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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, 524, 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: 21 U.S.C. 360b.

2. Section 522.770 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 522.770 Doramectin.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use*. For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata, Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

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PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

4. Section 524.770 is amended by revising paragraph (d)(2) to read as follows:

§ 524.770 Doramectin.

* * * * *

(d) * * *

(2) *Indications for use*. For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia, C. punctata,* and *Oesophagostomum radiatum* for 28 days after treatment.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

5. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

6. Section 556.225 is revised to read as follows:

§ 556.225 Doramectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of doramectin is 0.75 microgram per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle.* A tolerance of 100 parts per billion is established for parent doramectin (marker residue) in liver (target tissue) and of 30 parts per billion for parent doramectin in muscle.

(2) *Swine.* A tolerance is established for parent doramectin (marker residue) in liver (target tissue) of 160 parts per billion.

Dated: December 2, 1998.

Andrew J. Beaulieu,

Acting 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 8792]

RIN 1545–AV56

Qualified Long-Term Care Insurance Contracts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations relating to consumer protection with respect to qualified long-term care insurance contracts and relating to events that will result in the loss of grandfathered status for long-term care insurance contracts issued prior to January 1, 1997. Changes to the applicable law were made by the Health Insurance Portability and Accountability Act of 1996. The regulations affect issuers of long-term care insurance contracts and individuals entitled to receive payments under these contracts. The regulations are necessary to provide these taxpayers with guidance needed to comply with these changes.

DATES: *Effective date.* These regulations are effective December 10, 1998.

Applicability date. Section 1.7702B–1 (concerning consumer protection provisions) of the regulations applies with respect to contracts issued after December 10, 1999. Section 1.7702B–2 (concerning special rules for pre-1997 contracts) of the regulations is applicable January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Katherine A. Hossofsky, (202) 622–3477 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) to provide rules relating to consumer protection with respect to qualified long-term care insurance contracts and relating to events that will result in the loss of grandfathered status for long-term care insurance contracts issued prior to January 1, 1997.

A notice of proposed rulemaking (REG–109333–97) under section 7702B of the Code was published in the **Federal Register** on January 2, 1998 (63 FR 35). Written comments were received from the public, and a public hearing was held on May 13, 1998. After consideration of all the comments, the regulations proposed by REG–109333–97 are adopted as revised by this Treasury decision.

Explanation of Statutory Provisions

The Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191, 110 Stat. 1936, 2054 and 2063) (HIPAA) added section 7702B to the Internal Revenue Code of 1986 (the Code). Section 7702B establishes the tax treatment for qualified long-term care insurance contracts. Section 7702B(a)(1) and (3) of the Code provide that a qualified long-term care insurance contract is treated as an accident and health insurance contract and that any employer plan providing coverage under a qualified long-term care insurance contract is treated as an accident or health plan with respect to that coverage.

Section 7702B(a)(2) of the Code provides that amounts (other than policyholder dividends and premium refunds) received under a qualified long-term care insurance contract are generally excludable from gross income as amounts received for personal injuries and sickness.

Section 213(d)(1)(D) of the Code was amended by section 322 of HIPAA to provide that eligible long-term care insurance premiums, as defined in section 213(d)(10) of the Code, are medical care expenses.

Under section 7702B(b)(1)(F) of the Code, a qualified long-term care insurance contract must meet the consumer protection provisions of section 7702B(g) of the Code. In addition, section 4980C of the Code imposes an excise tax on issuers of qualified long-term care insurance contracts that do not provide further consumer protections.

Section 7702B of the Code applies to contracts issued after December 31, 1996. Section 321(f)(2) of HIPAA treats a contract issued before January 1, 1997, as a qualified long-term care insurance contract under section 7702B(b) of the Code, and services provided or reimbursed under such a contract as qualified long-term care services under section 7702B(c) of the Code, provided the contract met the long-term care insurance requirements of the State in which the contract was situsted at the time the contract was issued. Section 321(f)(2) of HIPAA also provides that in the case of an individual covered on December 31, 1996, by a State long-term care plan under section 7702B(f) of the Code, the terms of the plan on that date are treated as a contract meeting the long-term care insurance requirements of that State.

Section 321(f)(4) of HIPAA provides that for purposes of applying sections 101(f), 7702, and 7702A of the Code, neither the issuance of a rider that is treated as a qualified long-term care insurance contract nor the addition of any provision required to conform any other long-term care rider to the requirements applicable to a qualified long-term care insurance contract is treated as a modification or material change of the contract.

Explanation of Provisions

The final regulations provide guidance concerning

- The consumer protection requirements that apply to qualified long-term care insurance contracts under sections 7702B(g), 7702B(b)(1)(F), and 4980C of the Code; and
- The grandfather provisions of section 321(f)(2) of HIPAA under which pre-1997 contracts are treated as qualified long-term care insurance contracts if certain conditions are met.

The standards in the final regulations are based on safe harbors that were originally set forth in Notice 97–31 (1997–1 C.B. 417), and in the regulations proposed in REG–109333–97.

Notice 97–31

Notice 97–31 was issued to provide interim standards for taxpayers to use in interpreting the new long-term care provisions and to facilitate operation of the insurance market by avoiding the