

correcting amendment provides the complete language for 17 CFR 1.55(a)(1).

List of Subjects in 17 CFR Part 1

Commodity futures, Customer protection, Risk disclosure statements.

Accordingly, 17 CFR Part 1 is corrected by making the following correcting amendment:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 6p, 7, 7a, 8, 9, 12, 12a, 12c, 13a, 13a-1, 16, 16a, 19, 21, 23, 24.

2. In § 1.55, paragraph (a)(1) should be correctly revised to read as follows:

§ 1.55 Distribution of "Risk Disclosure Statement" by futures commission merchants and introducing brokers.

(a)(1) Except as provided in 1.65, no futures commission merchant, or in the case of an introduced account no introducing broker, may open a commodity futures account for a customer, other than for a customer specified in paragraph (f) of this section, unless the futures commission merchant or introducing broker first:

(i) Furnishes the customer with a separate written disclosure statement containing only the language set forth in paragraph (b) of this section (except for nonsubstantive additions such as captions) or as otherwise approved under paragraph (c) of this section; *Provided, however,* that the disclosure statement may be attached to other documents as the cover page or the first page of such documents and as the only material on such page; and

(ii) Receives from the customer an acknowledgment signed and dated by the customer that he received and understood the disclosure statement.

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Issued in Washington, D.C. on September 24, 1998 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 98-26078 Filed 9-29-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 intramuscular, intravenous, and subcutaneous use of oxytetracycline injection in lactating dairy cattle in addition to use in beef cattle, nonlactating dairy cattle, calves including preruminating (veal) calves, and swine.

EFFECTIVE DATE: September 30, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1652.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 113-232 that provides for intramuscular, intravenous, and subcutaneous use of Liqueamycin® LA-200® (oxytetracycline injection) for treatment of lactating dairy cattle in addition to treatment of beef cattle, nonlactating dairy cattle, calves including preruminating (veal) calves, and swine as in § 522.1660(d)(1) and (d)(2) (21 CFR 522.1660(d)(1) and (d)(2)). The supplemental NADA is approved as of July 21, 1998, and the regulations in § 522.1660(d)(1) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also § 522.1660(c) is revised to cross-reference the tolerances for oxytetracycline in 21 CFR 556.500. In addition, the tolerances are amended to provide for an acceptable daily intake (ADI) (see 61 FR 67453, December 23, 1996) and for a tolerance for residues in milk. Because the December 23, 1996, publication amends tolerances for all tetracyclines (chlortetracycline, oxytetracycline, and tetracycline), this document also amends 21 CFR 556.150 and 556.720 to reflect the tetracycline 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 this approval 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)), this supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning July 21, 1998, because the supplement contains substantial evidence of 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 supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of this drug in lactating dairy cattle for the labeled indications for which the supplemental application is approved.

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

21 CFR Part 522

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 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 522.1660 is amended by adding paragraph (c), by revising the heading in paragraph (d)(1) and the two last sentences in paragraph (d)(1)(iii) to read as follows:

§ 522.1660 Oxytetracycline injection.

* * * * *

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) * * *

(1) *Beef cattle, dairy cattle, and calves including preruminating (veal) calves.*

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(iii) * * * For sponsors 000010, 053389, 059130, and 061623: Not for use in lactating dairy cattle. For sponsor 000069: Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food; use subcutaneously with a maximum of 10 milliliters per injection site in adult cattle as well as intramuscularly and intravenously.

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

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

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

4. Section 556.150 is revised to read as follows:

§ 556.150 Chlortetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

(3) 12 ppm in fat and kidney.

5. Section 556.500 is revised to read as follows:

§ 556.500 Oxytetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobster, and salmonids.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

(3) 12 ppm in fat and kidney.

(4) 0.3 ppm in milk.

6. Section 556.720 is revised to read as follows:

§ 556.720 Tetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of tetracyclines including chlortetracycline, oxytetracycline, and tetracycline is 25 micrograms per kilogram of body weight per day.

(b) *Calves, swine, sheep, chickens, and turkeys.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

(3) 12 ppm in fat and kidney.

Dated: September 8, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-26081 Filed 9-29-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF COMMERCE**Patent and Trademark Office****37 CFR Parts 2 and 3**

RIN 0651-AA87

Miscellaneous Changes to Trademark Trial and Appeal Board Rules; Correction

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to the rules relating to discovery, motions, and the fee for recording documents, and to the title of Part 3 of Volume 37 of the Code of Federal Regulations.

EFFECTIVE DATE: September 30, 1998.

FOR FURTHER INFORMATION CONTACT:

Ellen J. Seeherman, Administrative Trademark Judge, Trademark Trial and Appeal Board, by telephone at (703) 308-9300, extension 206; or by mail marked to her attention and addressed to Assistant Commissioner for Trademarks, Box TTAB-No Fee, 2900 Crystal Drive, Arlington, Virginia 22202-3513; or by facsimile transmission marked to her attention and sent to (703) 308-9333.

SUPPLEMENTARY INFORMATION: On September 9, 1998, the Patent and Trademark Office published a final rule

entitled "Miscellaneous Changes to Trademark Trial and Appeal Board Rules" in the **Federal Register** (63 FR 48081).

There is an error on page 48093, column 2, in the discussion of the amendment of Section 2.127(a), which states that "if a motion for an extension of time to file a brief in response to a motion is denied, the time for responding to the motion for summary judgment may remain as specified under this section." The words "for summary judgment" should be deleted.

Section 2.120(a) was amended to clarify certain Board practices and to change certain provisions relating to discovery. When the final rule was printed, this section was incorrectly published as two paragraphs instead of one. Section 2.120(a) should appear as a single paragraph.

Section 2.127(a) was amended to, inter alia, provide that the Board may, in its discretion, consider a reply brief. As published, however, a comma was erroneously placed after the word "Board" rather than after the word "may."

Section 3.41 was amended in order to correct a cross-reference to the section relating to the fee for recording a trademark document. However, an earlier version of § 3.41 was inadvertently inserted. The version of § 3.41 as published in the **Federal Register** on October 10, 1997, 62 FR 53132, 1203 TMOG 63 (October 21, 1997), which became effective December 1, 1997, should be reinserted with the corrected cross-reference.

Finally, the title of Part 3 of Volume 37 of the Code of Federal Regulations was erroneously listed as "Rules of Practice in Trademark Cases." It should remain as "Assignment, Recording and Rights of Assignee."

List of Subjects**37 CFR Part 2**

Administrative practice and procedure, Patents, Trademarks.

37 CFR Part 3

Administrative practice and procedure, Patents, Trademarks.

Accordingly, 37 CFR Parts 2 and 3 are corrected as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 6.

2. Section 2.120(a) is correctly revised to read as follows: