the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before June 1, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

### X. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Division of Product Manufacture and Use, Chemistry Review Team, FDA, to the Division of Petition Control, FDA, concerning ''CAP 8C0253 (MATS M2.0 & 2.1): Ethicon, Inc. (Submission of November 26, 1997). Petition for the safe use of use of [sic] phthalocyaninato(2-) copper as a colorant for nonabsorbable sutures,'' dated January 26, 1998.

### List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 74 is amended as follows:

## PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 74 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 74.3045 is amended by revising the introductory text of paragraph (c)(1) to read as follows:

**§ 74.3045 [Phthalocyaninato(2-)] copper.**

* * * * *

(c) *Uses and restrictions.* (1) The color additive [phthalocyaninato(2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and *alpha*-hydro-*omega*- hydroxypoly(oxy-1,4-butanediyl), CAS Reg. No. 37282–12–5) nonabsorbable sutures for use in general and ophthalmic surgery, polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery, nonabsorbable sutures made from poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene) for general and ophthalmic surgery, and polymethylmethacrylate monofilament used as supporting haptics for intraocular lenses, subject to the following restrictions:

* * * * *

Dated: April 23, 1999.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 99–10917 Filed 4–29–99; 8:45 am]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510 and 522

### 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 an abbreviated new animal drug application (ANADA) filed by Pliva d.d. The ANADA provides for intramuscular use of oxytetracycline injection in swine and intramuscular and intravenous use in cattle for treatment of bacterial infections susceptible to oxytetracycline.

**EFFECTIVE DATE:** April 30, 1999.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

**SUPPLEMENTARY INFORMATION:** Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia, filed ANADA 200–232 that provides for the use of Geomycin 200 (oxytetracycline injection) for treatment of diseases caused by oxytetracycline susceptible organisms as follows: Intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*, and in sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*; intramuscular and intravenous use in cattle for the treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, foot rot and diptheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *E. coli*, wooden tongue caused by *Actinobacillus lignieresi*, leptospirosis caused by *L. pomona*, and wound infections and acute metritis caused by strains of streptococcal and staphylococcal organisms.

Approval of Pliva d.d.'s ANADA 200–232 for oxytetracycline injection is as a generic copy of Pfizer, Inc.'s NADA 113–232 for Liquamycin® LA–200® (oxytetracycline injection). ANADA 200–232 is approved as of February 12, 1999, and the regulations are amended in 21 CFR 522.1660(b) and (d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Because Pliva d.d. has not been previously listed in the animal drug regulations as the sponsor of an approved application, 21 CFR 510.600 is amended in paragraphs (c)(1) and (c)(2) to add entries for the firm.

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.

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 Part 510*

Administrative practices and procedures, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 522*

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 parts 510 and 522 are amended as follows:

## PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''Pliva d.d.'' and in the table in paragraph (c)(2) by numerically adding an entry for ''011722'' to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

* * * * *

(c) * * *

(1) * * *

| Firm name and address | Drug labeler code |
|---|---|
| * * * | * * * |
| Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia | 011722 |
| * * * | * * * |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * | * * * |
| 011722 | Pliva d.d., Ulica grada Vukovara 49, 10000 Zagreb, Croatia |
| * * * | * * * |

## 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.

**§ 522.1660 [Amended]**

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraphs (b) and (d)(2)(iii) by adding the number ''011722,'' after ''000069''.

Dated: April 21, 1999.

**George A. Mitchell,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 99–10793 Filed 4–29–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Parts 1, 20, and 25

**[TD 8819]**

**RIN 1545–AX14**

## Use of Actuarial Tables in Valuing Annuities, Interests for Life or Terms of Years, and Remainder or Reversionary Interests

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains regulations relating to the use of actuarial tables in valuing annuities, interests for life or terms of years, and remainder or reversionary interests. These regulations are necessary because section 7520(c)(3) directs the Secretary to update the actuarial tables to reflect the most recent mortality experience available. These regulations will effect the valuation of inter vivos and testamentary transfers of interests dependent on one or more measuring lives. 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 elsewhere in this issue of the **Federal Register.**

**DATES:** These regulations are effective May 1, 1999.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, William L. Blodgett, (202) 622–3090 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Background

This document contains amendments to the regulations revising certain tables used for the valuation of partial interests in property under section 7520 of the Internal Revenue Code of 1986 (Code) to reflect the most recent mortality experience available.

*In General*

Section 7520, effective for transfers for which the valuation date is after