

Inc., 2621 North Belt Hwy., St. Joseph, MO 64506, has filed ANADA 200-008 which provides for use of oxytetracycline injection as follows: intramuscular or intravenous use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline-intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*; pneumonia caused by *P. multocida*; and leptospirosis caused by *L. pomona*-intramuscular use in sows for control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

Boehringer Ingelheim's ANADA 200-008 for oxytetracycline injection (OXY-TET 200/BIO-MYCIN 200) is approved as a generic copy of Pfizer's NADA 113-232 for oxytetracycline injection (Liquamycin LA-200). The ANADA is approved as of November 16, 1994, and the regulations are amended by revising § 522.1660(b) and (c)(2)(iii) (21 CFR 522.1660(b) and (c)(2)(iii)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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 in 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 part 522 is 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:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.1660 is amended in paragraph (b) by adding the phrase "000010 and" before the number "000069", and in paragraph (c)(2)(iii) by revising the last sentence to read as follows:

#### § 522.1660 Oxytetracycline injection.

\* \* \* \* \*

(c) \* \* \*

(2) \* \* \*

(iii) \* \* \* Discontinue treatment at least 42 days prior to slaughter when provided by 000010 or 28 days prior to slaughter when provided by 000069.

Dated: December 21, 1994.

**Michael J. Blackwell,**

*Deputy Director, Post-market Surveillance and Compliance, Center for Veterinary Medicine.*

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### DEPARTMENT OF TRANSPORTATION

#### Federal Highway Administration

#### 23 CFR Part 655

[FHWA Docket No. 94-33]

RIN 2125-AD45

#### National Standards for Traffic Control Devices; Revision of the Manual on Uniform Traffic Control Devices; Temporary Traffic Signals

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** This document incorporates by reference an amendment to Part VI of the Manual on Uniform Traffic Control Devices (MUTCD). This amendment is intended to revise the section of the MUTCD concerning temporary traffic signals in order to permit the use of certain temporary signalling devices

that were inadvertently excluded by an earlier revision to Part VI. The MUTCD is recognized as the national standard for traffic control on all public roads. Public comments are invited on this action.

**DATES:** This interim final rule is effective January 4, 1995.

Comments must be submitted on or before March 6, 1995.

Incorporation by reference of the publications listed in the regulations is approved by the Director of the Federal Register as of January 4, 1995.

**ADDRESSES:** Submit written, signed comments to FHWA Docket No. 94-33, Federal Highway Administration, Office of the Chief Counsel, room 4232, HCC-10, 400 Seventh Street, SW., Washington, DC 20590. All comments received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m., e.t., Monday through Friday except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

**FOR FURTHER INFORMATION CONTACT:** Mr. Michael E. Robinson, Office of Highway Safety, (202) 366-0411, or Mr. Wilbert Baccus, Office of Chief Counsel, (202) 366-0780, Federal Highway Administration, 400 Seventh Street, SW., room 3419, Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., except Federal holidays.

**SUPPLEMENTARY INFORMATION:** The MUTCD is available for inspection and copying as prescribed in 49 CFR Part 7, appendix D. Part VI of the MUTCD may be purchased for \$16.00 from the Superintendent of Documents, U. S. Government Printing Office, Washington, DC 20402, Stock No. 050-001-00516-3.

The FHWA both receives and initiates requests for amendments to the MUTCD. Each request is assigned an identification number which indicates, by Roman numeral, the organizational part of the MUTCD affected and, by Arabic numeral, the order in which the request was received (e.g., Request VIII-9).

This amendment contains corrections to Part VI of the MUTCD, Standards and Guides for Traffic Control for Street and Highway Construction, Maintenance, Utility, and Incident Management Operations. Part VI sets forth principles and prescribes standards for temporary traffic control zone operations on streets and highways in the United States. Also, part VI addresses the design, administration, and operation of street and highway temporary traffic control plans and projects. Previous **Federal Register** actions regarding changes to