21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that was published in the **Federal Register** of July 10, 1996 (61 FR 36290), that amended the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) held by Boehringer Ingelheim Animal Health, Inc. The regulation inadvertently failed to specify that only Boehringer Ingelheim's oxytetracycline injection is approved for subcutaneous use in cattle. In addition, the preamble failed to provide that the supplemental approval was granted 3 years marketing exclusivity for the new use. This document corrects these errors.

EFFECTIVE DATE: July 10, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 10, 1996 (61 FR 36290), FDA published the approval of Boehringer Ingelheim Animal Health, Inc.'s supplemental ANADA 200–008 that provides for subcutaneous use of oxytetracycline injection in addition to the approved intravenous and intramuscular use in beef and nonlactating dairy cattle. The approval document inadvertently failed to specify that only Boehringer Ingelheim's oxytetracycline injection is approved for subcutaneous use in cattle. Accordingly, the agency is correcting 21 CFR 522.1660(c)(1)(iii) as set forth below.

In addition, the document did not state that under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), as in effect on May 22, 1996, the date of approval, this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning May 22, 1996, because the supplement contains reports of new clinical or field investigations other than bioequivalence, or residue studies, and in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) essential to the approval of the supplement and conducted or sponsored by the applicant.

§ 522.1660 [Corrected]

2. In FR Doc. 96–17541, appearing on page 36290 in the **Federal Register** of Wednesday, July 10, 1996, the following correction is made. On page 36291, in the first column, in line 2, amendment ''2.'' is corrected to read as follows:

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (c)(1)(iii) by removing the first sentence and adding two sentences in its place, to read as follows:

§ 522.1660 Oxytetracycline injection.

* * * * *

(c) * * *

(1) * * *

(iii) Administer intramuscularly or intravenously at the 3 to 5 milligrams level, intramuscularly at the 9 milligrams level. Sponsor 000010, may also administer subcutaneously at the 3 to 5 milligrams and 9 milligrams levels. * * *

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Dated: March 13, 1997.

Robert C. Livingston,

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

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 527

RIN 1120–AA53

[BOP–1058–F]

Transfer of Inmates to State Agents for Production on State Writs

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons is making various editorial or procedural changes in order to update its regulations on transfer of inmates to state agents for production on state writs.

EFFECTIVE DATE: March 24, 1997.

ADDRESSES: Office of General Counsel, Bureau of Prisons, HOLC Room 754, 320 First Street, NW., Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Roy Nanovic, Office of General Counsel, Bureau of Prisons, phone (202) 514–6655.

SUPPLEMENTARY INFORMATION: The Bureau of Prisons is amending its regulations on transfer of inmates to state agents for production on state writs (28 CFR part 527, subpart D). A final rule on this subject was published in the **Federal Register** July 1, 1981 (46 FR 34549) and was amended October 1, 1985 (50 FR 40105).

The Bureau is making various editorial or procedural changes in order to update § 527.31. Specifically, paragraph (a) is amended for the purpose of removing the instruction that the provisions of the rule may not be used to avoid the use, or to circumvent the intent, of the Interstate Agreement on Detainers. This requirement is more suitable for inclusion in implementing instructions to staff rather than in the regulatory text. Paragraph (c) is amended by revising the provisions governing how requests are to be made. These provisions previously had read that the request may be made by letter, or in urgent cases by wire or phone. The Bureau is revising this to require the request to be made by letter. Implementing instructions to staff further address how the letter may be received (for example, via facsimile transmission). Consequently, the regulation would not need to be further amended in order to recognize technological changes in accepting requests. Paragraph (d) is amended for editorial consistency (that is, in order to use the phrase ''institution staff'' rather than ''institutional staff''). Finally, paragraph (h) is amended by removing the phrase ''in either the Regional or Central Office'' and redundant regulatory information. Because the provisions in paragraph (h) serve as a cross-reference to the controlling regulations for Central Inmate Monitoring Cases, the inclusion of such specific information is unnecessary.

Because these changes are either administrative or editorial in nature, the Bureau finds good cause for exempting the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and delay in effective date. Members of the public may submit comments concerning this rule by writing to the previously cited address. These comments will be considered but will receive no response in the **Federal Register**.

The Bureau of Prisons has determined that this rule is not a significant regulatory action for the purpose of E.O. 12866, and accordingly this rule was not reviewed by the Office of Management and Budget. After review of the law and regulations, the Director, Bureau of Prisons has certified that this rule, for the purpose of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), does not have