

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
[FR Doc. 97-7277 Filed 3-21-97; 8:45 am]

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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

a significant economic impact on a substantial number of small entities, within the meaning of the Act. Because this rule pertains to the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, its economic impact is limited to the Bureau's appropriated funds.

List of Subjects in 28 CFR Part 527

Prisoners.

Kathleen M. Hawk,
Director, Bureau of Prisons.

Accordingly, pursuant to the rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons in 28 CFR 0.96(p), part 527 in subchapter B of 28 CFR, chapter V is amended as set forth below.

SUBCHAPTER B—INMATE ADMISSION, CLASSIFICATION, AND TRANSFER

PART 527—TRANSFERS

1. The authority citation for 28 CFR part 527 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3565, 3569, 3621, 3622, 3624, 4001, 4042, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4100–4115, 4161–4166 (Repealed as to offenses committed on or after November 1, 1987), 4201–4218, 5003, 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510; 28 CFR 0.95–0.99.

2. In § 527.31, paragraph (a) is amended by removing the second sentence, paragraph (c) is amended by revising the second sentence, paragraph (d) is amended by revising the second sentence, and paragraph (h) is revised to read as follows:

§ 527.31 Procedures.

* * * * *

(c) * * * The request shall be made by letter. * * *

(d) * * * Institution staff shall verify the authenticity of the writ.

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(h) Release of inmates classified as Central Inmate Monitoring Cases requires review with and/or coordination by appropriate authorities in accordance with the provisions of 28 CFR part 524, subpart F.

[FR Doc. 97-7292 Filed 3-21-97; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 223

Small Business Timber Sale Set-Aside Program; Appeal Procedures on Recomputation of Shares

AGENCY: Forest Service, USDA.

ACTION: Interim rule; request for comment.

SUMMARY: This interim rule provides an opportunity for timber purchasers to appeal the recomputation of the small business share of National Forest System Timber sales. The rule is necessary to implement a legislative requirement to provide timber purchasers the opportunity to comment on and appeal recomputation of shares and related decisions made under the Small Business Timber Sale Set-Aside Program.

DATES: *Effective Dates:* This rule is effective March 24, 1997, except for § 223.18 paragraph (f) which contains information collection requirements that have not been approved by the Office of Management and Budget. The Forest Service will publish a subsequent notice in the **Federal Register** announcing the effective date of the information collection requirements.

Comment Date: Comments on this interim rule must be received by May 23, 1997.

ADDRESSES: Send written comments to Director, Timber Management, MAIL STOP 1105, Forest Service, USDA, P.O. Box 96090, Washington, DC 20090-6090. Comments received, including name and address where provided, shall be placed in the record of the rulemaking and made available for copying and public inspection.

FOR FURTHER INFORMATION CONTACT: Rod Sallee, Timber Management Staff, (202) 205-1766.

SUPPLEMENTARY INFORMATION:

Background

Developed in cooperation with the Small Business Administration, the Forest Service Small Business Timber Sale Set-Aside Program is designed to ensure that qualifying small business timber purchasers have the opportunity to purchase a fair proportion of National Forest System timber offered for sale. The current set-aside program was adopted July 26, 1990 (55 FR 30485).

Under the program, the Forest Service must recompute the shares of timber sales to be set-aside for qualifying small businesses every five years based on the actual volume of sawtimber that has

been purchased and/or harvested by small businesses. Also, shares must be recomputed if there is a change in manufacturing capability, if the purchaser size class changes, or if certain purchasers discontinue operations. Direction to guide employees in administering the Small Business Timber Sale Set-Aside Program is issued in the Forest Service Manual, Chapter 2430, and Chapter 90 of the Forest Service Timber Sale Preparation Handbook (FSH) 2409.18.

In 1992, the agency adopted new administrative appeal procedures at 36 CFR part 215 in response to new statutory direction. These rules apply to all National Forest System project-level decisions for which an environmental assessment (EA) or impact statement (EIS) has been prepared. Because the recomputation of shares under the Small Business Set-Aside Program is not subject to documentation in an EA or EIS, the decisions on the 1996-2000 Forest Service recomputation of small business shares were not subject to the appeal procedures. However, since the agency had accepted appeals of recomputation decisions under 36 CFR part 217 prior to adoption of part 215, the agency decided to establish procedures for providing notice to affected purchasers with opportunity to comment on the recomputation of shares. Notice of these procedures was published in the **Federal Register** on February 28, 1996 (61 FR 7468).

The Conference Report accompanying the 1997 Omnibus Appropriation Act (Public Law 104-208) found the Forest Service decision to eliminate an administrative appeals opportunity for the Small Business Timber Sale Set-Aside Program "unacceptable" and directed the Forest Service to reinstate an appeals process before December 31, 1996. The Conference Report requires that the agency establish a process by which purchasers may appeal decisions concerning recomputations of SBA shares, structural recomputations of SBA shares, or changes in policies impacting the timber sale set-aside program. It also provides that, as in the past, decisions related to the designation of the sales to be set aside will not be open for appeal.

Good Cause Exemption

The Conference Report accompanying the FY 1997 Omnibus Appropriation Act directed reinstatement of the appeals process by December 31, 1996. The Department has determined that such reinstatement can occur only through informal rulemaking (5 U.S.C. 552). Regrettably, the Department was not able to meet the December deadline