

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsor
(i) 10 to 20 grams per ton of feed	Sheep: For increased rate of weight gain and improved feed efficiency		066104
(ii) To provide 0.05 to 0.1 mg/lb of body weight daily.	Calves (up to 250 lb): For increased rate of weight gain and improved feed efficiency	Feed continuously; in milk replacers or starter feed	066104
(iii) To provide 10 mg/lb of body weight daily	1. Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia (shipping fever complex) caused by <i>P. multocida</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin	Feed continuously for 7 to 14 d; in feed or milk replacers. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in prurminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter	066104
	2. Calves (up to 250 lb): For treatment of bacterial enteritis caused by <i>E. coli</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin	Feed continuously for 7 to 14 d; in milk replacers or starter feed. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in prurminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter	066104
	3. Sheep: For treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>P. multocida</i> susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by <i>E. coli</i> susceptible to neomycin	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 d, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter	066104
(iv) To provide 25 mg/head/day	Calves (250 to 400 lb): For increased rate of weight gain and improved feed efficiency		066104
(v) To provide 75 mg/head/day	Growing cattle (over 400 lb): For increased rate of weight gain; improved feed efficiency, and reduction of liver condemnation due to liver abscesses		066104
(vi) To provide 0.5 to 2.0 g/head/day	Cattle: For prevention and treatment of the early stages of shipping fever complex	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in prurminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older	066104

■ 5. In § 558.460, redesignate paragraphs (d)(2)(vi), (d)(2)(vii), and (d)(2)(viii) as paragraphs (d)(2)(iii), (d)(2)(v), and (d)(2)(vi); and add new paragraph (d)(2)(iv) to read as follows:

**§ 558.460 Penicillin.**

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(iv) Nicarbazin alone or with roxarsone as in § 558.366.

\* \* \* \* \*

Dated: March 22, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 814 and 820**

[Docket No. 2006N-0127]

**Medical Device Reporting; Premarket Approval of Medical Devices; Quality System Regulation; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this final rule to correct some inadvertent typographical errors and other minor errors in certain device regulations. FDA intends for these corrections to improve the accuracy of the agency's regulations.

**EFFECTIVE DATE:** March 31, 2006.

**FOR FURTHER INFORMATION CONTACT:** Philip Desjardins, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2343.

**SUPPLEMENTARY INFORMATION:**

**I. Highlights of Final Rule**

FDA is making the following changes to correct typographical and other minor errors in certain device regulations:

1. FDA is amending 21 CFR 814.126(b)(1)(iv) to replace "8dd" with "803."

2. FDA is amending 21 CFR 820.198(a)(3) to eliminate a reference to part 804, a part that does not exist.

**II. Environmental Impact**

The agency has determined under 21 CFR 25.30(i) 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.

**III. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule corrects only typographical errors in existing regulations and does not change in any way how devices are regulated, the agency certifies that the final rule will not have a significant economic impact

on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

**IV. Paperwork Reduction Act of 1995**

FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**V. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**VI. The Technical Amendments**

This rule corrects certain minor errors in existing regulations. This administrative action is limited to correcting typographical errors and eliminating a reference to a nonexistent Code of Federal Regulations (CFR) part. It makes no changes in substantive requirements.

Because the final rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely makes technical administrative changes in the CFR for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

**List of Subjects**

*21 CFR Part 814*

Administrative practice and procedure, Confidential business information, Institutional review board requirements, Medical devices, Medical research, Reporting and recordkeeping requirements.

*21 CFR Part 820*

Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 814 and 820 are amended as follows:

**PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES**

■ 1. The authority citation for 21 CFR part 814 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 2. Amend paragraph (b)(1)(iv) of § 814.126 by removing "part 8dd" and adding in its place "part 803".

**PART 820—QUALITY SYSTEM REGULATION**

■ 3. The authority citation for 21 CFR part 820 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

■ 4. Amend paragraph (a)(3) of § 820.198 by removing "or 804".

Dated: March 24, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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**DEPARTMENT OF STATE**

**22 CFR Part 17**

[Public Notice 5311]

**Overpayments From the Foreign Service Retirement and Disability Fund**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State is revising its regulations regarding overpayments from the Foreign Service Retirement and Disability Fund under the Foreign Service Retirement and Disability System (FSRDS) to reflect internal Department restructuring and realignment of responsibilities and the