

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

DDM

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Certifier A. Corbin

**Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur**

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Pharmacia & Upjohn Co. The supplemental NADAs provide for establishing a 4-day preslaughter withdrawal period in swine injected with either a solution made from ceftiofur sodium powder or with a ceftiofur hydrochloride suspension.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: [joan.gotthardt@fda.gov](mailto:joan.gotthardt@fda.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed supplements to NADA 140-338 for NAXCEL (ceftiofur sodium) Sterile Powder for Injection and to NADA 140-890 for EXCENEL RTU (ceftiofur hydrochloride) Sterile Suspension. The supplemental NADAs provide for establishing a 4-day preslaughter withdrawal period in swine injected with either product. The supplemental applications are approved as of June 18, 2004, and the regulations are amended in 21 CFR cv0438

140-890

NFR 1

522.313 and 522.314 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (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 these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required for either.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

### **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:

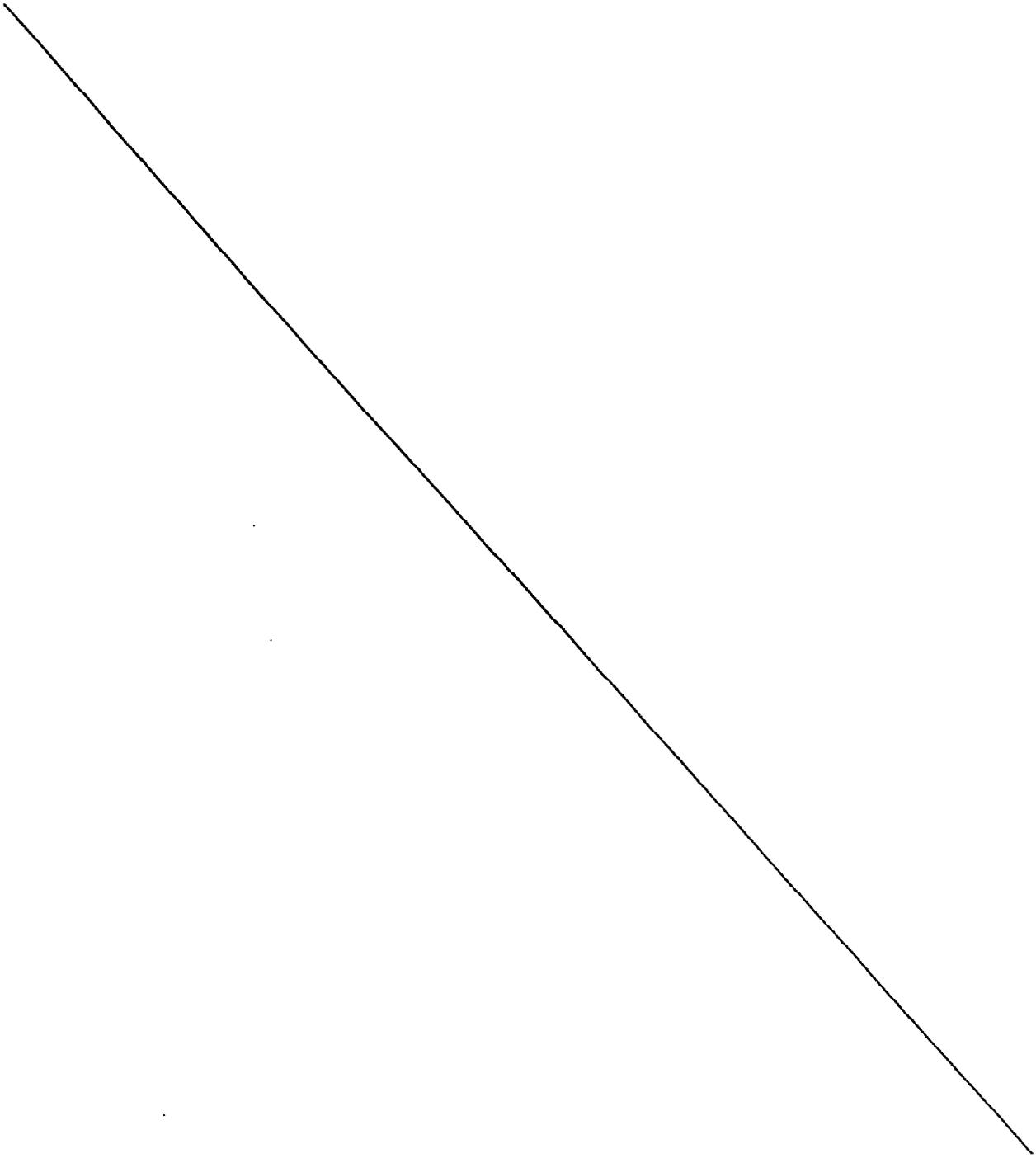
### **PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 522.313 [Amended]**

■ 2. Section 522.313 is amended in paragraph (d)(2)(iii) by adding “Treated swine must not be slaughtered for 4 days following the last treatment.” as the last sentence.



§ 522.314 [Amended]

■ 3. Section 522.314 is amended in paragraph (d)(1)(iii) by adding “Treated swine must not be slaughtered for 4 days following the last treatment.” as the last sentence.

Dated: July 21, 2004  
July 21, 2004.

Steven D. Vaughn  
Steven D. Vaughn,  
Director, Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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