

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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Certifier L. CLAWSON  
DDM

Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate  
Sodium Injection

**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 a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for a revised food safety warning on labeling for hyaluronate sodium injectable solution.

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

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 112-048 for HYLARTIN (sodium hyaluronate) Injection, approved for veterinary prescription use by intra-articular injection for the treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis. The supplemental NADA provides for a revised food safety warning on the labeling. The application is approved as of May 30, 2006, and the regulations are amended in 21 CFR 522.1145 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(d)(1) 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.

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**

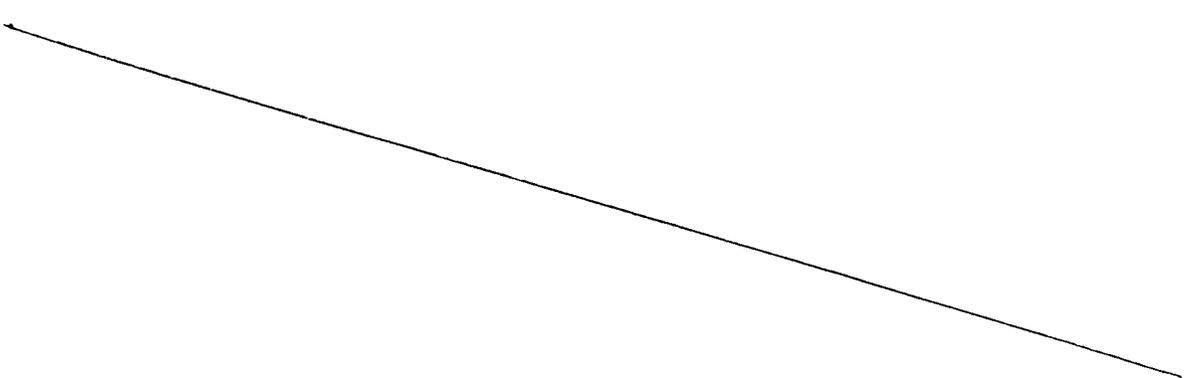
Animal drugs.

■ 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.



§ 522.1145 [Amended]

■ 2. In § 522.1145, in the heading remove the word “injection”; and in paragraph (a)(3)(iii) remove the sentence “Not for use in horses intended for food.” and add in its place “Do not use in horses intended for human consumption”.

Dated: June 27, 2006  
June 27, 2006.

Steven D. Vaughn  
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Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine.  
[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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