

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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 Bayer HealthCare LLC. The supplemental NADA provides for veterinary prescription use of a hyaluronate sodium solution, formulated with a benzyl alcohol preservative, for intravenous administration to horses for the treatment of osteoarthritis.

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, 301-827-7543, e-mail: melanie.berson@fda.gov.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 140-883 that provides for veterinary prescription use of LEGEND Multi-dose (hyaluronate sodium) Injectable Solution. The supplemental NADA provides for use of this hyaluronate sodium solution, formulated with a benzyl alcohol preservative, from a multi-dose vial for intravenous administration to horses for the treatment of carpal or fetlock osteoarthritis. The supplemental NADA

is approved as of December 15, 2005, and the regulations are amended in 21 CFR 522.1145 to reflect the approval and a current format. 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), a summary of safety and effectiveness data and information submitted to support approval of this application 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(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 Subject 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.

■ 2. Section 522.1145 is amended by revising paragraph (e) to read as follows:

§ 522.1145 Hyaluronate sodium injection.

* * * * *

(e)(1) *Specifications.* Each milliliter of solution contains:

(i) 10 milligrams (mg) hyaluronate sodium; or

(ii) 10 mg hyaluronate sodium with benzyl alcohol as a preservative.

(2) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(3) *Conditions of use in horses*—(i) *Amount.* 20 mg of the product described in paragraph (e)(1)(i) of this section by intra-articular injection into the carpus or fetlock; or 40 mg of the product described in paragraph (e)(1)(i) or (e)(1)(ii) of this section by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use.* For treatment of carpal or fetlock joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations*. Do not use in horses intended for human consumption.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Dated: January 4, 2005.

Steven D. Vaughn,

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

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