DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Sometribove Zinc Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Monsanto Co. The supplemental NADA provides for revised wording of the indication and precautionary labeling for sometribove zinc suspension used to increase the production of marketable milk in healthy lactating dairy cows. The regulations are also being amended to reflect a different drug labeler code (DLC) for Monsanto Co.

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

FOR FURTHER INFORMATION CONTACT: Suzanne J. Sechen, Center for Veterinary Medicine (HFV 126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0221, e-mail: *ssechen@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167, filed a supplement to NADA 140–872 that provides for the use of POSILAC (sometribove zinc suspension) to increase the production of marketable milk in healthy lactating dairy cows. The supplemental NADA provides for revised precautionary labeling. The application is approved as of September 11, 2003, and the regulations are amended in 21 CFR 522.2112 to

reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Monsanto Co. has changed their DLC. At this time, 21 CFR 510.600(c) is being amended to reflect this DLC change.

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(a)(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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''Monsanto Co.'' by removing ''059945'' and by adding in its place ''000911''; and in the table in paragraph (c)(2) by removing the entry for ''059945'' and by numerically adding an entry for ''000911'' to read ''Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Section 522.2112 is amended in paragraph (b) by removing ''059945'' and by adding in its place ''000911''; in paragraph (c)(1) by removing ''beginning'' and by adding in its place ''starting''; and by revising paragraphs (c)(2) and (c)(3) to read as follows:

§ 522.2112 Sometribove zinc suspension.

* * * * *

(c) * * *

(2) *Indications for use.* To increase production of marketable milk in healthy lactating dairy cows.

(3) *Limitations*. Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Inject subcutaneously. Avoid injections within 2 weeks of expected slaughter to minimize injection site blemishes on carcass. There is no milk discard or preslaughter withdrawal period. Use may reduce pregnancy rates and increase days open. Treated cows are at an increased risk for mastitis and higher milk somatic cell counts. Use care to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Cows treated with this product may have more enlarged hocks and disorders of the foot region. Use may reduce hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

Dated: October 10, 2003.

Steven D. Vaughn,

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

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