causing their proprietary capital ratios to be less than 30 percent. The extent to which the oil pipeline company has amounts loaned or money advanced to its parent, subsidiary, or affiliated companies through its cash management program(s) should also be reported, along with plans, if any, to regain at least a 30 percent proprietary capital ratio.

(d) In the event that the proprietary capital ratio subsequently meets or exceeds 30 percent, oil pipeline companies subject to the provisions of the Commission's Uniform System of Accounts prescribed in part 352 and § 357.2 of this title that participate in cash management programs must notify the Commission within 45 days after the end of each calendar quarter.

Note: This appendix will not be published in the *Code of Federal Regulations.*

Appendix

LIST OF COMMENTERS ON THE INTERIM RULE

Respondent	Abbreviation
Alliance Pipeline, LP	Alliance.
American Public Gas Association	APGA.
Association of Oil Pipe Lines	AOPL.
Chevron Pipe Line Company	CPL.
Cinergy Corporation	Cinergy.
Duke Energy Corporation	Duke Energy.
Edison Electric Institute	EEI.
El Paso Corporation's Pipeline Group	El Paso.
Exelon Corporation	Exelon.
First Energy Corporation	FirstEnergy.
Graham County Electric Cooperative, Inc	GCEC.
Gulf South Pipeline Company, LP	Gulf South.
Gulfterra Energy Partners, LP	Gulfterra.
Interstate Natural Gas Association of America	INGAA.
National Rural Electric Cooperative Association	NRECA.
National Grid USA	National Grid.
National Association of Regulatory Utility Commissioners	NARUC (late comment).
NiSource Inc	NiSource.
OKTex Pipe Line Co	OKTex.
PacifiCorp	PacifiCorp.
The PSEG Companies.	
Shell Pipeline Company LP	Shell.
Sierra Southwest Cooperative Services, Inc	SSW.
Southern California Edison Company	Edison.
Tucson Electric Power Company	Tucson.
Williams Pipe Line Company, LLP	WPL.

[FR Doc. 03–27410 Filed 10–30–03; 8:45 am]
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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 October 31, 2003.

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.

[FR Doc. 03–27395 Filed 10–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

New Animal Drugs; Altrenogest

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 new animal drug application (NADA) filed by Intervet, Inc. The NADA provides for use of an altrenogest oral solution in gilts for synchronization of estrus.

DATES: This rule is effective October 31, 2003.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV 128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301 827–1600, *e-mail: candres@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed NADA 141–222 for the oral use of MATRIX (altrenogest) 0.22% Solution for synchronization of estrus in sexually mature gilts that have had at least one estrous cycle. The NADA is approved as of September 30, 2003, and the regulations are amended in 21 CFR 520.48 and in part 556 (21 CFR part 556) by adding § 556.36 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), 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 carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 30, 2003.

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 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 520 and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.48 is amended by revising paragraphs (c) and (d) to read as follows:

§ 520.48 Altrenogest solution.

* * * * *

(c) *Tolerances.* See § 556.36 of this chapter.

(d) Conditions of use—(1)*Horses*—(i)*Amount.* 1.0 mL per 110 pounds body