and (l) as paragraphs (g), (h), (i), (j), and (k).

3. Section 703.50 is amended by revising paragraph (b)(2) to read as follows:

§ 703.50 What rules govern my dealings with entities I use to purchase and sell investments (''broker-dealers'')?

* * * * *

(b) * * *

(2) Information available from state or federal securities regulators and securities industry self-regulatory organizations, such as the National Association of Securities Dealers and the North American Securities Administrators Association, about any enforcement actions against the broker-dealer, its affiliates, or associated personnel.

* * * * *

4. Section 703.100 is amended by revising paragraph (e) to read as follows:

§ 703.100 What investments and investment activities are permissible for me?

* * * * *

(e) You may invest in fixed or variable rate CMOs/REMICs.

* * * * *

5. Section 703.130 is revised to read as follows:

§ 703.130 May I continue to hold investments purchased before January 1, 1998, that will be impermissible after that date?

(a) Subject to safety and soundness considerations, you may hold a CMO/REMIC residual, SMBS, or zero coupon security with a maturity greater than 10 years, if you purchased the investment:

(1) Before December 2, 1991; or

(2) On or after December 2, 1991, but before January 1, 1998, if for the purpose of reducing interest rate risk and you meet the following:

(i) You have a monitoring and reporting system in place that provides the documentation necessary to evaluate the expected and actual performance of the investment under different interest rate scenarios;

(ii) You use the monitoring and reporting system to conduct and document an analysis that shows, before purchase, that the proposed investment will reduce your interest rate risk;

(iii) After purchase, you evaluate the investment at least quarterly to determine whether or not it actually has reduced your interest rate risk; and

(iv) You classify the investment as either trading or available-for-sale.

(b) All grandfathered investments are subject to the valuation and monitoring requirements of §§ 703.70, 703.80, and 703.90.

PART 704—CORPORATE CREDIT UNIONS

6. The authority citation for part 704 continues to read as follows:

Authority: 12 U.S.C. 1757(7), 1757(8), 1757(15).

7. Section 704.5 is amended by revising paragraph (c)(6) to read as follows:

§ 704.5 Investments.

* * * * *

(c) * * *

(6) CMOs/REMICs.

* * * * *

Appendix B to Part 704—[Amended]

8. Appendix B to part 704 is amended as follows:

a. A heading is added to the beginning of the Appendix; and

b. In Part I paragraph (c)(6) is removed and paragraphs (c)(7) through (c)(9) are redesignated as paragraphs (c)(6) through (c)(8); and

c. In Part II paragraph (c)(6) is removed and paragraphs (c)(7) and (c)(8) are redesignated as paragraphs (c)(6) and (c)(7).

The addition reads as follows:

Appendix B to Part 704—Expanded Authorities and Requirements

Part I

* * * * *

[FR Doc. 98–11450 Filed 4–30–98; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

Certain Other Dosage Form New Animal Drugs; Isoflurane

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 an abbreviated new animal drug application (ANADA) filed by Marsam Pharmaceuticals, Inc. The ANADA provides for inhalational use of isoflurane USP for induction and maintenance of general anesthesia in horses and dogs.

EFFECTIVE DATE: May 1, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034, filed ANADA 200–187 that provides for inhalational use of isoflurane USP for induction and maintenance of general anesthesia in horses and dogs. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200–187 for Marsam Pharmaceuticals, Inc.'s, isoflurane is as a generic copy of Ohmeda Pharmaceutical Product's NADA 135–773 AErrane® (isoflurane, USP). The ANADA is approved as of February 11, 1998, and the regulations are amended in 21 CFR 529.1186(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Marsam Pharmaceuticals, Inc., has not been previously listed in § 510.600 (21 CFR 510.600) as sponsor of an approved application. The regulations are amended in § 510.600(c)(1) and (c)(2) to reflect the new sponsor.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20855, 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.

List of Subjects

21 CFR Part 510

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

21 CFR Part 529

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 529 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.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''Marsam Pharmaceuticals, Inc.,'' and in the table in paragraph (c)(2) by numerically adding an entry for ''000209'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * * *
Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.	000209
* * *	* * * * *

(2) * * *

Drug labeler code	Firm name and address
* *	* * * * *
000209	Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.
* *	* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

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

2. Section 529.1186 is amended by revising paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 000074, 000209, 010019, 012164, and 059258 in § 510.600(c) of this chapter.

* * * * *

Dated: April 22, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–11685 Filed 4–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Spectinomycin Solution

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 Pharmacia & Upjohn Co. The NADA provides for veterinary prescription use of spectinomycin solution as a subcutaneous injection in cattle for treatment of bovine respiratory disease.

EFFECTIVE DATE: May 1, 1998.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199, filed NADA 141–077 that provides for veterinary prescription use of Adspec™ (spectinomycin) sterile solution for cattle, by subcutaneous injection in the neck, for treatment of bovine respiratory disease (pneumonia) associated with *Pasteurella haemolytica, P. multocida,* and *Haemophilus somnus.* The NADA is approved as of January 28, 1998, and the regulations are amended by adding § 522.2121 (21 CFR 522.2121) to reflect the approval.

A tolerance for residues of spectinomycin in edible tissues of cattle has not been previously established. The regulations are amended in 21 CFR 556.600 to provide a tolerance for spectinomycin residues in cattle kidney (target tissue) and in cattle muscle.

FDA is also amending the regulations to provide for the acceptable daily intake (ADI) for total residues of spectinomycin. The ADI is the amount of total drug residue that can be consumed by humans every day. Previously, FDA had provided for safe concentrations, which represent the ADI corrected for consumption. The safe concentrations were confusing because few individuals understood the relationship between safe concentration, a value representing total residues, and tolerance, the part of the drug residue in a given tissue that is detected by an analytical method. To eliminate this confusion, FDA is codifying the ADI.

Also, the heading of § 522.2120 *Spectinomycin injection* (21 CFR 522.2120) is revised to ''§ 522.2120 *Spectinomycin dihydrochloride injection*'' to clarify the difference between § 522.2120 and § 522.2121 *Spectinomycin sulfate solution.*

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.