Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

This rule exempts horses imported into the United States from Iceland from the requirement for testing for dourine, glanders, equine piroplasmosis, and EIA during the quarantine period. As explained previously in this document, we have determined that there is a negligible risk of horses imported from Iceland introducing dourine, glanders, equine piroplasmosis, and EIA into the United States.

As a result of this rule, U.S. importers of horses from Iceland will no longer be required to have those horses tested for dourine, glanders, equine piroplasmosis, and EIA during the quarantine period. The test for EIA costs $5; the tests for equine piroplasmosis cost $9 for each strain for a total of $18; the test for dourine costs $9; and the test for glanders costs $9. Therefore, importers will save a total of $41 on each horse imported from Iceland. Horses imported from Iceland will still be required to undergo a 3-day quarantine after arrival in the United States and undergo any other tests and procedures that may be required by APHIS to determine their freedom from communicable diseases.

According to the 1997 Census of Agriculture, the United States had a total population of at least 2,427,277 horses in that year. In 1999, the United States exported 78,702 horses valued at $293 million, and imported 30,398 horses valued at $326 million. However, only 166 (less than 1 percent) of those horses were imported from Iceland. The total number of horses imported from Iceland is small due in part to the prices of these horses, which averaged $4,367. All of the horses imported from Iceland in 1999 were nonpurebred horses. As a comparison, nonpurebred horses imported from Canada into the United States had an average value of $1,450 in 1999.

The overall economic impact of this rule will be minimal. Importers will save on the importation of horses, but the overall savings will be small. Had this rule been in place in 1999 and applied to the 166 horses imported from Iceland in that year, importers would have saved a total of $6,806.

APHIS does not expect that the number of horses imported from Iceland into the United States will increase significantly as a result of this rule. The cost reduction associated with this rule is less than 1 percent of the average price of horses imported from Iceland into the United States in 1999. Therefore, this rule is expected to have only minimal economic effects on U.S. importers of horses from Iceland, regardless of their size.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 93 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. In § 93.308, paragraph (a)(3) is revised to read as follows:

§ 93.308 Quarantine requirements.

(a) * * *

(3) To qualify for release from quarantine, all horses, except horses from Iceland, must test negative to official tests for dourine, glanders, equine piroplasmosis, and equine infectious anemia.[14] However, horses imported from Australia and New Zealand are exempt from testing for dourine and glanders. In addition, all horses must undergo any other tests, inspections, disinfections, and precautionary treatments that may be required by the Administrator to determine their freedom from communicable diseases.

* * * * *

Done in Washington, DC, this 31st day of October 2001.

W. Ron DeHaven,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01–27816 Filed 11–5–01; 8:45 am]

BILLING CODE 3410–34–U

[14] Because the official tests for dourine and glanders are performed only at the National Veterinary Services Laboratories in Ames, IA, the protocols for those tests have not been published and are, therefore, not available; however, copies of ''Protocol for the Complement-Fixation Test for Equine Piroplasmosis'' and ''Protocol for the Immunno-Diffusion (Coggins) Test For Equine Infectious Anemia'' may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import-Export, 4700 River Road Unit 38, Riverdale, MD 20737–1231.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

Change of Address; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change in the address for the Center for Food Safety and Applied Nutrition (CFSAN). This action is editorial in nature and is intended to improve the accuracy of the agency's regulations.

EFFECTIVE DATE: December 14, 2001.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning, and Legislation (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR parts 1, 5, 10, 70, 71, 73, 80, 100, 101, 102, 106, 107, 108, 109, 110, 130, 161, 165, 170, 172, 173, 175, 176, 177, 178, 180, 181, 184, 189, 190, 211, 701, 1240, and 1250 to reflect a change in the address for CFSAN. The current address listed in the above regulations is 200 C Street, SW., Washington, DC 20204. The

new address is 5100 Paint Branch Pkwy., College Park, MD 20740.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

1. Parts 1, 5, 10, 70, 71, 73, 80, 100, 101, 102, 106, 107, 108, 109, 110, 130, 161, 165, 170, 172, 173, 175, 176, 177, 178, 180, 181, 184, 189, 190, 211, 701, 1240, and 1250 are amended by removing ''200 C Street, SW., Washington, DC 20204'' or ''200 C St. SW., Washington, DC 20204'' wherever they appear and by adding in their place ''5100 Paint Branch Pkwy., College Park, MD 20740.''

Dated: October 31, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–27811 Filed 11–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Marsam Pharmaceuticals, Inc., to Marsam Pharmaceuticals, LLC.

DATES: This rule is effective November 6, 2001.

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, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034, has informed FDA of a change of sponsor's name to Marsam Pharmaceuticals, LLC. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's name.

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 510

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

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 510 is 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 ''Marsam Pharmaceuticals, Inc.'' and in the table in paragraph (c)(2) in the entry for ''000209'' by removing ''Inc.'' and by adding in its place ''LLC''.

Dated: October 26, 2001.

Claire M. Lathers,

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

[FR Doc. 01–27813 Filed 11–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Elanco Animal Health, A Division of Eli Lilly & Co., to Ivy Laboratories, Div. of Ivy Animal Health, Inc.

DATES: This rule is effective November 6, 2001.

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: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, has informed FDA that it has transferred to Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, ownership of, and all rights and interests in NADA 118–123 for COMPUDOSE 200 (estradiol) and COMPUDOSE 400 implants for cattle. Accordingly, the agency is amending the regulations in 21 CFR 522.840 to reflect the transfer of ownership.

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.

§ 522.840 [Amended]

2. Section 522.840 *Estradiol* is amended in paragraph (b) by removing ''000986'' and by adding in its place ''No. 021641''.

Dated: October 26, 2001.

Claire M. Lathers,

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

[FR Doc. 01–27812 Filed 11–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 100 and 165

[USCG–2001–10936]

Safety Zones, Security Zones, and Special Local Regulations

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary rules issued.