''List of substances'' and ''Limitations'' to read as follows:

§ 178.3400 Emulsifiers and/or surface active agents.

(c) * * *

* * * * *

List of substances	Limitations
* * *	* * * *
Sulfosuccinic acid 4-ester with polyethylene glycol nonylphenyl ether, disodium salt (alcohol moiety produced by condensation of 1 mole nonylphenol and an average of 9–10 moles of ethylene oxide) (CAS Reg. No. 9040–38–4).	For use only at levels not to exceed 5 percent by weight of the total coating monomers used in the emulsion polymerization of polyvinyl acetate and vinyl-acrylate copolymers intended for use as coatings for paper and paperboard.
* * *	* * * *

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Dated: May 15, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14296 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; 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 the change of sponsor for an approved new animal drug application (NADA) from Deprenyl Animal Health, Inc., to Pfizer, Inc.

EFFECTIVE DATE: June 1, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Deprenyl Animal Health, Inc., 7101 College Blvd., suite 580, Overland Park, KS 66210, has informed FDA that it has transferred the ownership of, and all rights and interests in, the approved NADA 141–080 (selegiline hydrochloride tablets) to Pfizer, Inc., 235 East 42d St., New York, NY 10017. The agency is amending 21 CFR 510.600(c)(1) and (c)(2) to remove the sponsor name for Deprenyl Animal Health, Inc., because the firm no longer is the holder of any approved NADA's. The agency is also amending 21 CFR 520.2098 to reflect the change of sponsor.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520

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 520 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) by removing the entry for ''Deprenyl Animal Health, Inc.''; and in the table in paragraph (c)(2) by removing the entry for ''063248''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.2098 [Amended]

4. Section 520.2098 *Selegiline hydrochloride tablets* is amended in paragraph (b) by removing ''063248'' and by adding in its place ''000069''.

Dated: May 12, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–14299 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Lufenuron Suspension

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 Novartis Animal Health US, Inc. The NADA provides for subcutaneous use of lufenuron suspension in cats for control of flea populations.

EFFECTIVE DATE: June 1, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., P.O. Box 26402, Greensboro, NC 27404–6402, is the sponsor of NADA 141–105 that provides for the subcutaneous use of Program™ (lufenuron) 10 percent sterile suspension for cats for the control of flea populations. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of March 13, 1998, and the regulations are amended by adding § 522.1289 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 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.

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.

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 March 13, 1998, because the application contains substantial evidence of the effectiveness of the drug involved or studies of target animal safety required for approval of the application and conducted or sponsored by the applicant.

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.

2. Section 522.1289 is added to read as follows:

§ 522.1289 Lufenuron suspension.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 10 milligrams of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Cats*—(i) *Amount.* 10 milligrams per kilogram (4.5 milligrams per pound) of body weight every 6 months, subcutaneously.

(ii) *Indications for use.* For use in cats 6 weeks of age and older, for control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

(iii) *Limitations.* For subcutaneous use in cats only. The safety of this product in reproducing animals has not been established. Do not use in dogs. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: May 12, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–14298 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 96N–0119]

Amended Economic Impact Analysis of Final Rule Requiring Use of Labeling on Natural Rubber Containing Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; amended economic analysis statement.

SUMMARY: The Food and Drug Administration (FDA) is issuing an amended economic analysis statement relating to a final rule that published in the **Federal Register** of September 30, 1997 (62 FR 51021), requiring labeling statements concerning the presence of natural rubber latex in medical devices. This rule was issued in response to numerous reports of severe allergic reactions and deaths related to a wide range of medical devices containing natural rubber. The final rule becomes effective on September 30, 1998. In order to allow further comment on the economic impact of the September 30, 1997 final rule, FDA is publishing an amended economic impact statement, including an amended initial regulatory flexibility analysis (IRFA) that it has prepared under the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement and Fairness Act (SBREFA). FDA will respond to comments to this amended economic analysis statement, and publish in the **Federal Register** an amended final economic impact statement prior to the effective date of the September 30, 1997 rule.

DATES: Submit written comments by July 1, 1998 on this amended economic analysis statement.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket numbers found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–443–2444, FAX 301–443–2296.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA published a final rule (to be codified at 21 CFR 801.437), under its authority in section 505(a) and (f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a) and (f)), requiring certain labeling statements on medical devices that contain or have packaging that contains natural rubber. This rule becomes effective on September 30, 1998. The agency issued this rule because medical devices composed of natural rubber may pose a significant health risk to some consumers and health care providers who are sensitized to natural latex proteins. FDA has received numerous reports about adverse effects related to reactions to natural latex proteins contained in medical devices, including 16 deaths following barium enemas. These deaths were associated with anaphylactic reactions to the natural rubber latex cuff on the tip of barium enema catheters. Scientific studies and case reports have documented sensitivity to natural latex proteins found in a wide range of medical devices. It is estimated that 5 to 17 percent of health care workers are sensitive to latex proteins (Refs. 1 through 5).

The September 30, 1997 rule (hereinafter referred to as the final rule) specifically requires that devices that contain natural rubber that is intended to contact or is likely to contact the health care worker or patient bear one or more of four labeling statements, depending on the type of natural rubber in the device and depending on whether the natural rubber is in the device itself or in its packaging. These statements are as follows: ''This Product Contains Dry Natural Rubber.''; ''Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.''; ''The Packaging of This Product Contains Dry Natural Rubber.''; and ''The Packaging of This Product Contains Natural Rubber Latex Which