(3) *Conditions of use.* (i) Copolyester-graft acrylate copolymer described in paragraph (c)(1) of this section is intended to improve the adhesive qualities of film. It is limited for use as a modifier of Nylon 6 and Nylon 6 modified with Nylon MXD–6 at a level not to exceed 0.17 weight percent of the additive in the finished film.

(ii) The finished film is used for packaging, transporting, or holding all types of foods under conditions of use B through H, described in Table 2 of § 176.170(c) of this chapter, except that in the case of Nylon 6 films modified with Nylon MXD–6 (complying with § 177.1500, item 10.2), the use complies with the conditions of use specified in Table 2.

(iii) *Extractives.* Food contact films described in paragraphs (c)(1) of this section, when extracted with solvent or solvents prescribed for the type of food and under conditions of time and temperature specified for the intended use, shall yield total extractives not to exceed 0.5 milligram per inch squared of food-contact surface when tested by the methods described in § 176.170(d) of this chapter.

(iv) *Optional adjuvant substances.* The substances employed in the production of Nylon modifiers listed in paragraph (c)(1) of this section may include:

(A) Substances generally recognized as safe for use in food and food packaging;

(B) Substances subject to prior sanction or approval for use in Nylon resins and used in accordance with such sanctions or approval; and

(C) Optional substances required in the production of the additive identified in this paragraph and other optional substances that may be required to accomplish the intended physical or technical effect.

Dated: April 2, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–10909 Filed 4–25–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

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 a change of sponsor for three new animal drug applications (NADA's) from Ciba-Geigy Animal Health, Ciba-Geigy Corp. to Novartis Animal Health US, Inc.

EFFECTIVE DATE: April 28, 1997.

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: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA's 140–915, 141–026, and 141–035 to Novartis Animal Health US, Inc., P.O. Box 18300, Greensboro, NC 27419–8300. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing Ciba-Geigy Animal Health, Ciba-Geigy Corp., because the firm is no longer the sponsor of any approved NADA's, and by alphabetically adding a new listing for Novartis Animal Health US, Inc. The drug labeler code assigned is being retained for the new sponsor.

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: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376e).

§ 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 ''Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300'' and by alphabetically adding a new entry for ''Novartis Animal Health US, Inc.''; and in the table in paragraph (c)(2) in the entry for ''058198'' by removing the sponsor name ''Ciba-Geigy Animal Health, Ciba-Geigy Corp.'' and adding in its place ''Novartis Animal Health US, Inc.''

Dated: April 8, 1997.

Robert C. Livingston,

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

[FR Doc. 97–10912 Filed 4–25–97; 8:45 am]

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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 a new abbreviated animal drug application (ANADA) from Phoenix Pharmaceutical, Inc., to Phoenix Scientific, Inc.

EFFECTIVE DATE: April 28, 1997.

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: Phoenix Pharmaceutical, Inc., 4621 Easton Rd., P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457, has informed FDA that it has transferred ownership of, and all rights and interests in, approved ANADA 200–042 (ketamine hydrochloride injection) to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457. Accordingly, the agency is amending the regulations in 21 CFR 522.1222a to reflect the change of sponsor.

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: