Regulation pursuant to delegated authority (12 CFR 265.7(f)(10)), April 23, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–10838 Filed 4–25–97; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

21 CFR Part 177

[Docket No. 96F–0213]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol, (Σ)-2-butenedioic acid, 1,2-ethanediol, ethyl 2-propenoate, hexanedioic acid and 2-propenoic acid, graft, in Nylon 6 and Nylon 6 modified with Nylon MXD–6 articles intended for use in contact with food. This action is in response to a petition filed by Toyobo Co., Ltd.

DATES: Effective April 28, 1997; written objections and requests for a hearing by May 28, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 18, 1996 (61 FR 37484), FDA announced that a food additive petition (FAP 6B4511) had been filed by Toyobo Co., Ltd., 2–1–1 Hon Katata Otsu, Shiga 520–02, Japan. The petition proposed to amend the food additive regulations in § 177.1500 *Nylon resins* (21 CFR 177.1500) to provide for the safe use of 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol, (Σ)-2-butenedioic acid, 1,2-ethanediol, ethyl 2-propenoate, hexanedioic acid, and 2-propenoic acid, graft, in Nylon 6 and Nylon 6 modified with Nylon MXD–6 articles intended for use in contact with food. The graft resins of this type are generically called copolyester-graft-acrylate copolymer.

During the agency's review of the petition, the agency observed that the nomenclature for (Σ)-2-butenedioic acid was incorrect. The correct nomenclature is (*E*)-2-butenedioic acid. This document uses the correct designation for the subject component in the codified final rule.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will have its intended technical effect, and therefore, that the regulations in § 177.1500 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. No comments were received during the 30-day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

Any person who will be adversely affected by this regulation may at any time on or before May 28, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.1500 is amended by redesignating paragraph (c) as paragraph (d), by adding a new paragraph (c), and in the last sentence of newly designated paragraph (d)(5)(ii) by removing the phrase ''paragraph (c)(5)(i)'' and adding in its place the phrase ''paragraph (d)(5)(i)'' to read as follows:

§ 177.1500 Nylon resins.

* * * * *

(c) *Nylon modifier*—(1) *Identity.* Copolyester-graft-acrylate copolymer is the substance 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol, (*E*)-2-butenedioic acid, 1,2-ethanediol, ethyl 2-propenoate, hexanedioic acid and 2-propenoic acid, graft (CAS Reg. No. 175419–23–5), and is derived from grafting of 25 weight percent of acrylic polymer with 75 weight percent of copolyester. The copolyester is polymerized terephthalic acid (55 mol%), adipic acid (40 mol%), and fumaric acid (5 mol%) with ethylene glycol (40 mol%) and 1,4-butanediol (60 mol%). The acrylic polymer is made from acrylic acid (70 mol%) and ethyl acrylate (30 mol%).

(2) *Specifications.* The finished copolyester-graft-acrylate copolymer shall meet the following specifications:

(i) Weight average molecular weight 15,000–35,000,

(ii) pH 7.2 to 8.2, and

(iii) Glass transition temperature –15 to –25 °C.

(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: