(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]

BILLING CODE 4160–01–F

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]

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; 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:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1222a [Amended]

2. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing the number ''057319'' and adding in its place ''059130''.

Dated: March 31, 1997.

Robert C. Livingston,

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

[FR Doc. 97–10914 Filed 4–25–97; 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; Flunixin Meglumine

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 Agri Laboratories, Ltd. The ANADA provides for use of flunixin meglumine injection in horses for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–061, which provides for intravenous or intramuscular use of flunixin meglumine injection in horses for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic. Flunixin meglumine is for veterinary prescription use only.

Approval of ANADA 200–061 for Agri Laboratories' flunixin meglumine injection is as a generic copy of Schering-Plough's Banamine® (flunixin meglumine) Solution (injection) NADA 101–479. The ANADA is approved as of September 11, 1996, and the regulations are amended in 21 CFR 522.970(b) to reflect the approval. The basis for 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 firm has submitted an abbreviated environmental assessment. In response, FDA has prepared a finding of no significant impact. The agency has determined under 21 CFR 25.24(d)(1)(i) 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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.970 is amended by revising paragraph (b) to read as follows:

§ 522.970 Flunixin meglumine solution.

* * * * *

(b) *Sponsors.* See Nos. 000061, 000856, 057561, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–10910 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate

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 Med-Pharmex, Inc. The ANADA provides for the use of gentamicin sulfate solution in the dipping treatment of turkey hatching eggs as an aid in the reduction or elimination of certain organisms.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, has filed ANADA 200–191, which provides for use of Gentasol (gentamicin sulfate solution) in the dipping treatment of turkey hatching eggs as an aid in the reduction or elimination of the following organisms from turkey hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, and *Mycoplasma meleagridis*.

The ANADA is approved as a generic copy of Schering Plough's NADA 92–523, Garasol® Solution (gentamicin sulfate veterinary). ANADA 200–191 is approved as of March 24, 1997, and the regulations are amended in 21 CFR 529.1044b to reflect the approval. The basis for 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 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,