Substances	Limitations
* * *	* * * * *
3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane (CAS Reg. No. 154862–43–8).	For use only: 1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, 2.3, 3.1, or 3.2 (where density of each of these polymers is greater than 0.94 gram per cubic centimeter) and under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.06 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, item 3.1 or 3.2, having a density less than 0.94 gram per cubic centimeter and under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * * *

Dated: May 15, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–14105 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

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 five new animal drug applications (NADA's) from Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065 to Koffolk, Inc.

EFFECTIVE DATE: May 29, 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: Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065, has informed FDA that it has transferred ownership of, and all rights and interests in, the following NADA's to Koffolk, Inc., One Parker Plaza, Fort Lee, NJ 07024:

NADA No.	Ingredient
9–476	NICARB 25%
98–378	Nicarbazin-Bacitracin Methylene Disalicylate
107–997	Nicarbazin-Roxarsone-Lincomycin Medicated Feed
108–115	Nicarbazin-Roxarsone
108–116	Nicarbazin-Lincomycin

Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by alphabetically adding a new listing for Koffolk, Inc. The agency is also amending § 558.366 to reflect the transfer of ownership.

List of Subjects

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, animal feeds.

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 558 are 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, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Koffolk, Inc.,'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''063271'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Koffolk, Inc., One Parker Plaza, Fort Lee, NJ 07024	063271
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
063271	Koffolk, Inc., One Parker Plaza, Fort Lee, NJ 07024
* * *	* * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.366 [Amended]

4. Section 558.366 *Nicarbazin* is amended in paragraph (a) by removing ''000006, 000986, and 060728'' and adding in its place ''000986, 060728, and 063271'' and in the table in paragraph (c), under the ''Sponsor'' column in the entry for ''113.5 (0.0125 pct)'' by removing the number ''000006'' and numerically adding ''063271'', and in the same column in the items ''Bacitracin methylene disalicylate 30,'' ''Lincomycin 2 (0.00044 pct),'' ''Roxarsone 22.7 (0.0025),'' and ''Roxarsone 22.7 (0.0025) plus lincomycin 2 (0.0004)'' by removing the number ''000006'' and numerically adding ''063271''.

Dated: May 16, 1997.

Robert C. Livingston,

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

[FR Doc. 97–14101 Filed 5–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral 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 Phoenix Scientific, Inc. The ANADA provides use of gentamicin sulfate pig pump oral solution for the control and treatment of colibacillosis in neonatal pigs 1 to 3 days of age.

EFFECTIVE DATE: May 29, 1997.

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: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–174, which provides for the control and treatment of colibacillosis in neonatal pigs 1 to 3 days of age caused by strains of *Escherichia coli* sensitive to gentamicin.

The ANADA is approved as a generic copy of Schering-Plough Animal Health's, Garason® Pig Pump (gentamicin sulfate oral solution) NADA 130–464. ANADA 200–174 is approved as of April 10, 1997, and the regulations are amended in 21 CFR 520.1044b 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, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1044b [Amended]

2. Section 520.1044b *Gentamicin sulfate pig pump oral solution* is amended in paragraph (b) by adding