

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUB

Display Date	12-6-01
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Certifier	J Reese

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for six approved new animal drug applications (NADAs) from Koffolk, Inc., to Phibro Animal Health.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067, has informed FDA that it has transferred ownership of, and all rights and interest in, the following NADAs to Phibro Animal Health, 710 Rte. 46 East, suite 401, Fairfield, NJ 07004.

NADA Number	Established Names of Ingredients
9-476	Nicarbazin
98-378	Nicarbazin/Bacitracin Methylene Disalicylate
107-997	Nicarbazin/Lincomycin/Roxarsone
108-115	Nicarbazin/Roxarsone
108-116	Nicarbazin/Lincomycin
141-146	Nicarbazin/Bacitracin Zinc

Accordingly, the agency is amending the regulations in 21 CFR 558.366 to reflect the transfer of ownership.

Following the change of sponsor of these NADAs, Koffolk, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove the entries for this sponsor.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

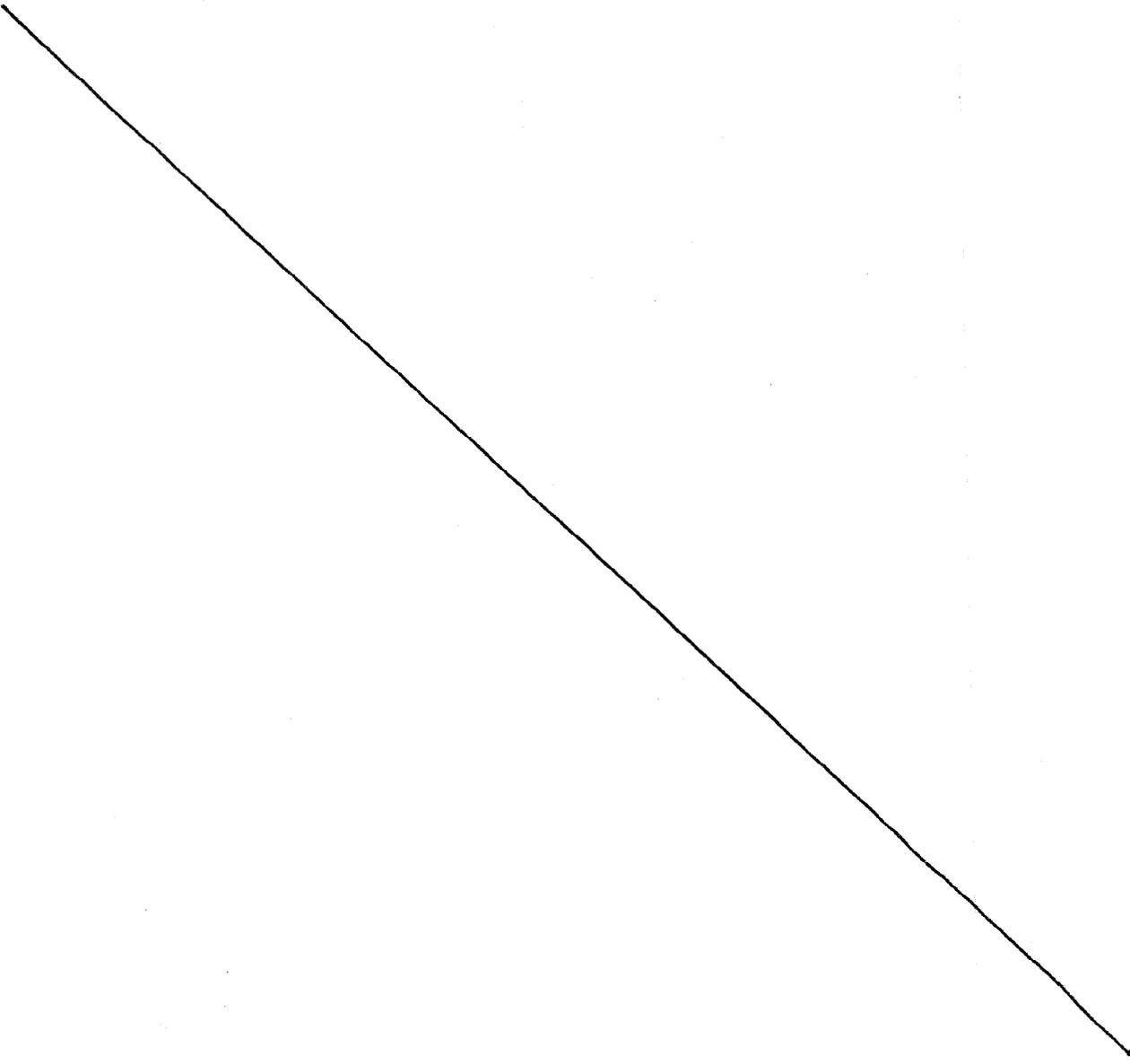
2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry “Koffolk, Inc.,” and in the table in paragraph (c)(2) by removing the entry “063271”.

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: 21 U.S.C. 360b, 371.

4. Section 558.366 is amended by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively; by revising paragraph (a); by adding a new paragraph (b); and in the newly redesignated paragraph (d), in the table, under the headings "Limitations" and "Sponsor" by removing "063271" wherever it appears and by adding in its place "066104" to read as follows:



§ 558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Approvals.* See Nos. 000986, 060728, and 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

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Dated: 11/15/01
November 15, 2001.

Claire M. Lathers

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