2. New § 341.70 is added to subpart C to read as follows:

§ 341.70 Labeling of OTC drug products containing ingredients that are used for treating concurrent symptoms (in either a single-ingredient or combination drug product).

The statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *For products containing diphenhydramine citrate and diphenhydramine hydrochloride identified in § 341.14(a)(5) and (a)(6).* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''antihistamine/cough suppressant'' or ''antihistamine/antitussive (cough suppressant).'' The indications shall be combined from §§ 341.72(b) and 341.74(b). The warnings shall be combined from §§ 341.72(c)(1), (c)(2), (c)(4), and (c)(6) and 341.74(c)(1), (c)(2), (c)(3), and (c)(4). Alternatively, all of the warnings in § 341.74(c) shall be used. The directions for OTC labeling shall follow §§ 341.74(d)(1)(iv) or (d)(1)(v), as applicable. The directions for professional labeling shall follow § 341.90(j) or (k), as applicable.

(b) (Reserved)

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8761 Filed 4–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name

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 name from A. L. Pharma, Inc., to ALPHARMA INC.

EFFECTIVE DATE: April 9, 1996.

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: A. L. Pharma, Inc., One Executive Dr., Fort Lee, NJ 07024, has informed FDA of a change of sponsor name to ALPHARMA INC. Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

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, 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 for ''A. L. Pharma, Inc.'' and by alphabetically adding a new entry for ''ALPHARMA INC.'' and in the table in paragraph (c)(2) in the entry ''046573'' by removing the sponsor name ''A. L. Pharma, Inc.'' and adding in its place ''ALPHARMA INC.''

Dated: March 28, 1996.

Robert C. Livingston,

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

[FR Doc. 96–8762 Filed 4–8–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 573

[Docket No. 90F–0297]

Food Additives Permitted in Feed and Drinking Water of Animals; Formaldehyde

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 formaldehyde (37 percent aqueous solution), at the rate of 5.4 pounds per ton (2.5 kilograms per ton) (lb/t) (kg/t) as an antimicrobial food additive for maintaining complete poultry feeds salmonella negative for up to 14 days. This action is in response to a food additive petition filed by Anitox Corp.

DATES: Effective April 9, 1996; written objections and requests for hearing by May 9, 1996.

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

FOR FURTHER INFORMATION CONTACT: Daniel G. McChesney, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1728.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of October 18, 1990 (55 FR 42272), FDA announced that a food additive petition (FAP 2215) had been filed by Anitox Corp., P.O. Box 1929, Buford, GA 30518. The petition proposed to amend the food additive regulations in § 573.460 *Formaldehyde* (21 CFR 573.460) to provide for the safe use of formaldehyde as an antimicrobial agent against bacteria, mold, and yeast in feed, at a level of 1.65 to 2.65 pounds per ton for fishmeal and animal byproduct meals, and at a level of 0.66 to 1.32 pounds per ton for complete feeds or feed ingredients. The notice of filing of FAP 2215 provided for a 60-day comment period. No comments have been received.

The sponsor amended the petition since it was originally filed. The amended petition proposed that § 573.460 be amended to provide for the safe use of formaldehyde (37 percent aqueous solution), at the rate of 5.4 lb/t (2.5 kg/t), as an antimicrobial food additive for maintaining complete poultry feeds salmonella negative for up to 14 days.

FDA has evaluated data in the petition and other relevant material. FDA concludes that the proposed food additive use of formaldehyde (37 percent aqueous solution) as an antimicrobial for maintaining complete poultry feeds salmonella negative for up to 14 days is safe. Therefore, the food additive regulations in § 573.460 is amended.

Formaldehyde can be life threatening if improperly handled. The proposed label for formaldehyde (37 percent aqueous solution) acknowledges this fact and identifies the product as a poison. The label provides for worker safety and further minimizes safety concerns for persons handling formaldehyde by containing adequate directions for use, strong cautionary statements about potential adverse respiratory effects, information about emergency aid in case of inhalation,