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,

ingestion or skin or eye contact, statements reflecting requirements of applicable sections of the National Environmental Protection Act (NEPA), the Superfund Amendments and Reauthorization Act (SARA), the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations, and a contact address and telephone number for reporting adverse reactions experienced by users or to request a copy of the Material Safety Data Sheet (MSDS). These worker safety concerns are required by other regulations.

In accordance with § 571.1(h) (21 CFR 571.1(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 Veterinary Medicine by appointment with the information contact person listed above. As provided in 21 CFR 571.1(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.

Any person who will be adversely affected by this regulation may at any time on or before May 9, 1996, 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 573

Animal feeds, Food additives.

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 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

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

2. Section 573.460 is amended by redesignating paragraphs (a) introductory text, (a)(1), (a)(2), (b), (c) introductory text, (c)(1), and (c)(2) as paragraphs (a)(1), (a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), (a)(3)(i), and (a)(3)(ii) respectively; and by adding new paragraph (b) to read as follows:

§ 573.460 Formaldehyde.

* * * * *

(b)(1) The food additive is formaldehyde (37 percent aqueous solution). It is used at the rate of 5.4 pounds (2.5 kilograms) per ton of poultry feed. At this level, it is an antimicrobial agent used to maintain complete poultry feeds salmonella negative for up to 14 days.

(2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) A statement that formaldehyde solution which has been stored below 40 °F or allowed to freeze should not be applied to complete poultry feeds.

(iii) Adequate directions for use including a statement that formaldehyde should be thoroughly mixed into complete poultry feed and that the finished poultry feed shall be labeled as containing formaldehyde.

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:(i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation, ingestion or skin or eye contact.

(iv) Statements reflecting requirements of applicable sections of the National Environmental Protection Act (NEPA), the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

Dated: March 11, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–8760 Filed 4–8–96; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN52–1–6978a; FRL–5452–4]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: On August 8, 1995, the State of Indiana submitted a State Implementation Plan (SIP) revision request to the United States Environmental Protection Agency (USEPA) for rule changes specific to Richmond Power and Light's (RPL's) Whitewater Generating Station located in Wayne County in Richmond, Indiana. The submittal provides for less stringent limits on particulate matter (PM) emissions than those currently in the SIP from both of the generating station's two primary boilers. The submittal also adds a combined PM limit for those times when both boilers are operating, establishes a site-specific opacity limit for the facility, and specifies a site-specific method for evaluating PM stack test results. The submittal includes air quality modeling which shows that the National Ambient Air Quality Standards (NAAQS) will still be protected under the new regulations.

DATES: The ''direct final'' rule is effective on June 10, 1996, unless USEPA receives adverse or critical comments by May 9, 1996. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the revision request are available for inspection at