SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that gives the responsibility to perform the centralized investigative activities in FDA to another office. The responsibility was recently transferred from the Division of Ethics and Program Integrity, Office of Management and Operations, FDA, to the Office of Internal Affairs, FDA. This action will codify this transfer of functions.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Tommy L. Hampton, Office of Internal Affairs (HF–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0243.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 23, 1995 (60 FR 4417), the Department of Health and Human Services published a notice to reflect an organizational change in FDA. The positions assigned to perform the centralized investigative activities located in the Division of Ethics and Program Integrity, Office of Management, Office of Management and Systems, FDA, were transferred to the new Office of Internal Affairs within the Office of the Commissioner.

The new Office of Internal Affairs will serve as an FDA investigative resource to conduct internal FDA investigations and support the Office of Inspector General investigations. Therefore, the agency is amending 21 CFR 19.21 to reflect the organizational change.

List of Subjects in 21 CFR Part 19

Conflict of interests.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 19 is amended as follows:

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

1. The authority citation for 21 CFR part 19 continues to read as follows:

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

2. Section 19.21 is amended in paragraph (a) by removing ''Division of Ethics and Program Integrity, Office of Management and Operations'' and adding in its place ''Office of Internal Affairs, Office of the Commissioner'' ; in paragraph (b) by removing ''Division of Ethics and Program Integrity'' the two times it appears and adding in its place ''Office of Internal Affairs''; and in paragraph (c) by removing ''Division of Ethics and Program Integrity'' and adding in its place ''Office of Internal Affairs''.

Dated: September 5, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–22636 Filed 9–12–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 175

[Docket No. 93F–0276]

Indirect Food Additives: Adhesives and Components of Coatings

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 ethoxylated primary linear alcohols of greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000 for use as components of food packaging adhesives. This action is in response to a petition filed by Petrolite Corp.

DATES: Effective September 13, 1995; written objections and requests for a hearing October 13, 1995.

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

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 17, 1993 (58 FR 48659), FDA announced that a food additive petition (FAP 3B4390) had been filed by Petrolite Corp., 369 Marshall Ave., St. Louis, MO 63119–1897. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of ethoxylated primary linear alcohols of greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000 for use as components of food packaging adhesives.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, carcinogenic impurities, resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called ''general safety clause'' of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer or Delaney clause (section 409(c)(3)(A) of the act) further provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott* v. *FDA* 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, ethoxylated primary linear alcohols of no greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000, will result in exposure to the additive of no greater than 50 parts per billion (ppb) in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data from acute toxicity studies on the additive. No adverse effects were reported in these studies.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additive,

1,4-dioxane and ethylene oxide. This risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of the worst-case exposure to the impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

A. 1,4-Dioxane

FDA has estimated the hypothetical worst-case exposure to 1,4-dioxane from the petitioned use of the additive in the manufacture of adhesives to be 0.25 part per trillion of the daily diet or 750 picogram (pg)/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay on 1,4-dioxane conducted by the National Cancer Institute (Ref. 3), to estimate the upper-bound lifetime human risk from exposure to this chemical stemming from the proposed use of the additive (Ref. 3). The results of the bioassay on 1,4-dioxane demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the estimated worst-case exposure of 750 pg/ person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the use of the subject additive is 2.7×10^{-11}, or 2.7 in 100 billion (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime averaged individual exposure to 1,4-dioxane is expected to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to 1,4-dioxane would result from the proposed use of the additive.

B. Ethylene Oxide

FDA estimated that the hypothetical worst-case exposure to ethylene oxide from the potential use of the additive in the manufacture of adhesives to be 0.05 part per trillion of the daily diet or 150 pg/person/day (Ref. 1). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany, to estimate the upper-bound level of lifetime human risk from exposure to ethylene oxide stemming from the proposed use of the additive (Ref. 5). The results of the bioassay on ethylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study. The test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas in situ of the glandular stomach.

Based on a potential exposure of 150 pg/person/day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to ethylene oxide from the use of the subject additive is 2.8×10^{-10}, or 2.8 in 10 billion (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the worst-case exposure, and therefore, the calculated upper-bound limit of risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to ethylene oxide would result from the proposed use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,4-dioxane and ethylene oxide may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely small levels; and (2) the upper-bound limits of lifetime risk from exposure to these impurities, even under worst-case assumptions, are very low, less than 2.7 in 100 billion for 1,4-dioxane and less than 2.8 in 10 billion for ethylene oxide, respectively.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of the additive in adhesives is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, § 175.105 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(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 Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

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.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before October 13, 1995, 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.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216), concerning FAP 3B4390—Petrolite Corp.—exposure to the food additive and its component (1,4-dioxane and ethylene oxide), November 5, 1993.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in ''Chemical Safety Regulation and Compliance,'' edited by F. Homburger and J. K. Marquis, S. Karger, New York, NY, pp. 24–33, 1985.

3. ''Bioassay of 1,4–Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

4. Memorandum, Report of the Quantitative Risk Assessment Committee, June 30, 1994.

5. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2–Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46:924, 1982.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding a new entry under the heading ''Substances'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Ethoxylated primary linear alcohols of greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000 (CAS Reg. No. 97953–22–5).	
* * * * *	

Dated: September 1, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–22637 Filed 9–12–95; 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 of approved applications from Animal Sciences Division of Monsanto Co. to Protiva, A Unit of Monsanto Co.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Judith M. O'Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: Animal Sciences Division of Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167, has informed FDA of a change of sponsor name to Protiva, A Unit of Monsanto Co. 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 ''Animal Sciences Division of Monsanto Co.'' and by alphabetically adding a new entry for ''Protiva, A Unit of Monsanto Company,'' and in the table in paragraph (c)(2) in the entry for ''059945'' by removing the sponsor name ''Animal Sciences Division of Monsanto Co.'' and adding in its place ''Protiva, A Unit of Monsanto Company.''

Dated: September 1, 1995.

Robert C. Livingston,

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

[FR Doc. 95–22638 Filed 9–12–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 640

[FHWA Docket No. 95–19]

RIN 2125–AD62

Certification Acceptance

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: The FHWA is adopting an interim policy for certification acceptance (CA) which modifies the current FHWA policy. The interim policy streamlines and simplifies the existing procedures for CA applications to be consistent with the new program provisions in sections such as 1016(f) and 1105(e) of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub. L. 102–240, 105 Stat. 1914. The modifications simplify the current regulations by eliminating unnecessary and prescriptive requirements. The new policy will allow State highway agencies (SHAs) to use the CA alternate procedures to supplement the administrative flexibility provided in the ISTEA for non-Interstate projects.

DATES: This regulation is effective September 13, 1995. Written comments must be received on or before December 12, 1995.

ADDRESSES: Submit written, signed comments to FHWA Docket No. 95–19, Federal Highway Administration, Room 4232, HCC–10, 400 Seventh Street SW., Washington, DC 20590. All comments received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m., e.t., Monday through Friday. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Donald J. Marttila, Interstate and Program Support Branch, Federal-Aid and Design Division, Office of Engineering, (202) 366–4637, or Mr. Wilbert Baccus, Office of the Chief Counsel, (202) 366–0780, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590.