DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 99F–1581]

Indirect Food Additives: Paper and Paperboard Components

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 imidazolium compounds, 2–(C_{17} and C_{17}-unsaturated alkyl)-1–[2–(C_{18} and C_{18}-unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates as a debonding agent in the manufacture of paper and paperboard intended for use in contact with aqueous and fatty food and in contact with dry food. This action is in response to a petition filed by Witco Corp.

DATES: This rule is effective June 12, 2000. Submit written objections and requests for a hearing by July 12, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), 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 June 4, 1999 (64 FR 30038), FDA announced that a food additive petition (FAP 9B4669) had been filed by Witco Corp., One American Lane, Greenwich, CT 06831–2559. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) and § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of imidazolium compounds, 2–(C_{17} and C_{17}-unsaturated alkyl)-[2–(C_{18} and C_{18}-unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates as a debonding agent in the manufacture of paper intended for use in contact with food. The name of the additive was incorrect in the June 4, 1999, notice, but is being used correctly as imidazolium compounds, 2–(C_{17} and C_{17}-unsaturated alkyl)-1–[2–(C_{18} and C_{18}-unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates in this document.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in §§ 176.170 and 176.180 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 § 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.

The agency has carefully considered the environmental effects of this rule as announced in the notice of filing for the petition. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by July 12, 2000. 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 are to be submitted and are to 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 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
* * * * * * *	
Imidazolium compounds, 2–(C_{17} and C_{17}-unsaturated alkyl)-1–[2–(C_{18} and C_{18}-unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates (CAS Reg. No. 72749–55–4).	For use only at a level not to exceed 0.5 percent by weight of the dry paper and paperboard.
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3. Section 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
* * * *	* * *
Imidazolium compounds, 2–(C_{17} and C_{17}-unsaturated alkyl)-1–[2–(C_{18} and C_{18}-unsaturated amido)ethyl]-4,5-dihydro-1-methyl, methyl sulfates (CAS Reg. No. 72749–55–4).	For use only at levels not to exceed 0.5 percent by weight of the dry paper and paperboard.
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Dated: May 31, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–14700 Filed 6–9–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

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's address for ADM Animal Health & Nutrition Division.

DATES: This rule is effective June 12, 2000.

FOR FURTHER INFORMATION CONTACT: Norman J. Turner, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0214.

SUPPLEMENTARY INFORMATION: ADM Animal Health & Nutrition Division, P.O. Box 2508, Fort Wayne, IN 46801–2508, has informed FDA of a change of sponsor's address to 1000 North 30th St., Box 1C, Quincy, IL 62305–3115. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor's address.

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 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: 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 revising the entry for ''ADM Animal Health & Nutrition Division'' and in the table in paragraph (c)(2) by revising the entry for ''017519'' 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
* * * *	* * *
ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305–3115	017519
* * * *	* * *

(2) * * *

Drug labeler code	Firm name and address
* * * *	* * *
017519	ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305–3115
* * * *	* * *