

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100.1(d)	1	1	1	40	40

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.1(d) is insignificant because petitions for exemption from preemption are seldom submitted by States requesting the agency grant an exemption from preemption by labeling requirements based upon certain sections of the act. Over the last 3 years, FDA has not received any preemption petitions. Since the enactment of section 403A(b) of the act as part of the Nutrition Labeling and Education Act of 1990, FDA has received only eight petitions for seeking exemption from preemption. Although FDA believes that the burden will be insignificant, it believes these information collection provisions should be extended to provide for the potential future need of a State or local government to petition for an exemption from preemption under the provisions of section 403A(b) of the act.

Dated: May 22, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99-14145 Filed 6-3-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food And Drug Administration

[Docket No. 99F-1581]

Witco Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Witco Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of imidazolium compounds,

2-(C₁₇ and C₁₇-unsaturated alkyl)-[2-(C₁₈ and C₁₈-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.

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: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4669) has been filed by Witco Corp., One American Lane, Greenwich, CT 06831-2559. The petition proposes 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-(C₁₇ and C₁₇-unsaturated alkyl)-[2-(C₁₈ and C₁₈-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 agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 20, 1999.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-14148 Filed 6-3-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225-98-8003]

Agreed Minutes; Meeting Between the Food and Drug Administration and the Health Authorities of Switzerland

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of agreed minutes between FDA and health authorities of Switzerland. The purpose of the agreed minutes is to continue and enhance cooperation in the fields of drugs, medical devices, and biological products consistent with FDA's framework for achieving mutual recognition of good manufacturing practices inspections.

DATES: The agreement became effective August 7, 1998.

FOR FURTHER INFORMATION CONTACT: Patrick Wilson, Office of International Affairs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108 (c), which states that all written agreements and understandings between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of these agreed minutes.

Dated: May 27, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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