TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

[1]There 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]

BILLING CODE 4160–01–F

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 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.

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-(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 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]

BILLING CODE 4160–01–F

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.

BILLING CODE 4160–01–F

225-98-8003

MEETING BETWEEN SWISS AND UNITED STATES DELEGATIONS ON REGULATORY COOPERATION

Agreed minutes

Delegations of officials of the United States and Switzerland met in Washington, D.C., on July 9, 1998, to discuss strengthening regulatory cooperation between the health authorities of both countries in the fields of drugs, medical devices, and biological products. The discussions were held in a very open and constructive atmosphere and led to the following common understanding.

Both countries are committed to safeguarding the public health, enhancing public health protection, and reducing the regulatory burden in commerce in safe, effective and good quality drugs, medical devices, and biological products. Switzerland and the U.S. agreed to continue and enhance cooperation in the fields of drugs, medical devices, and biological products between the U.S. Food and Drug Administration (FDA) and the Swiss health authorities (Intercantonal Office for the Control of Medicines and Federal Office of Public Health), consistent with FDA's framework for achieving mutual recognition of good manufacturing practices inspections. (This framework was made public on May 10, 1998, and is available on the internet on FDA's home page.)

In order to achieve the goal of enhanced regulatory cooperation, a working program should be established between both countries and should contain as a first step the following elements, subject to the availability of resources and with maximum use of information already available on the Internet home pages of the participating regulatory authorities:

- intensifying/formalizing information exchange, in particular in the field of adverse reactions, quality defects and product recalls;

- provide Swiss authorities with access to COMSTAT (FDA's Compliance Status Information System) and provide for FDA's access to any similar electronic information system maintained by Swiss authorities;

- consider ways to build confidence in the other country's regulatory program as a first step toward more reliance on each other's activities; the following projects will be pursued:

  exchange of inspection findings (for instance form FDA-483) and inspection reports upon request;

use of joint inspections (for the purpose of observing each other's activities) and inspectional history, and

joint training of inspectors;

- promote the harmonization of technical requirements and auditing techniques;
- designation of contact points and definition of their respective tasks.

The plan is for a work plan to be agreed upon by the end of December 1998. Switzerland plans to forward a first proposal by the end of October.

Oscar Zosso, Ambassador
Head of Swiss Delegation

for Sharon Smith Holston
FDA Deputy Commissioner
for External Affairs

Washington, D.C.
August 7, 1998

[FR Doc. 99–14146 Filed 6–3–99; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1540]

Draft Guidance for Reviewers on Evaluation of Human Pregnancy Outcome Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for reviewers entitled ''Evaluation of Human Pregnancy Outcome Data.'' The draft guidance is intended to provide the FDA clinical reviewer with factors to consider when systematically evaluating pregnancy outcome data related to maternal drug exposure. The draft guidance will be discussed during the June 3, 1999, meeting of the Subcommittee of the Advisory Committee for Reproductive Health Drugs.

DATES: Written comments on the draft guidance document may be submitted by September 2, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for reviewers are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; ''http://www.fda.gov/cber/guidelines.htm'' ; FAX: 1–888–CBERFAX or 301–827–3844; Mail: the Voice Information System at 800–835–4709 or 301–827–1800.

FOR FURTHER INFORMATION CONTACT:

Rose E. Cunningham, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5468; or
Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via e-mail at ''stifano@cber.fda.gov''.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for reviewers entitled ''Evaluation of Human Pregnancy Outcome Data.''

As part of its evaluation of pregnancy labeling, in September 1997 the agency held a 21 CFR part 15 hearing on the current category requirements for pregnancy labeling (see 62 FR 41061, July 31, 1997). The agency sought comment on the practical utility, effects, and limitations of the pregnancy categories. The agency sought input on ways to address problems, including possible alternatives to the categories for communicating information on reproductive and developmental toxicity.

Subsequently, the agency has been working on the development of various