ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	.5	1	.5	4,500	2,250
107.240	.5	1	.5	1,482	741
107.250	.5	1	.5	120	60
107.260	.5	1	.5	650	325
Total				6,752	3,376

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

No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been three recalls in the last 6 years, or 0.5 recalls annually.

Dated: August 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–20439 Filed 8–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93F–0269]

Lonza, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B4392) proposing that the food additive regulations be amended to provide for the safe use of didecyldimethylammonium chloride as a slimicide used in the manufacture of paper and paperboard intended to contact food.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 24, 1993 (58 FR 44682), FDA announced that a food additive petition (FAP 3B4392) had been filed by Lonza, Inc., c/o Delta Analytical Corp., 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814 (currently c/o Lewis & Harrison, 122 C St. NW., suite 740, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 176.300 *Slimicides* (21 CFR 176.300) to provide for the safe use of didecyldimethylammonium chloride as a slimicide used in the manufacture of paper and paperboard intended to contact food. Lonza, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 19, 1996.

Alan M. Rulis,

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

[FR Doc. 96–20437 Filed 8–9–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96G–0264]

FMC Corp.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that FMC Corp. has filed a petition (GRASP 6G0418) proposing to affirm that the use of konjac flour is generally recognized as safe (GRAS) as an ingredient in human food.

DATES: Written comments by October 28, 1996.

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

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that FMC Corp., 1735 Market St., Philadelphia, PA 19103, has filed a petition (GRASP 6G0418) proposing that konjac flour be affirmed as GRAS for use as an ingredient in human food.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Interested persons may, on or before October 28, 1996, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the

subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 9, 1996.

George H. Pauli,

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

[FR Doc. 96–20438 Filed 8–9–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Food Advisory Committee

Date, time, and place. August 27 and 28, 1996, 8:15 a.m., Marriott Hotel–Metro Center, Grand Ballroom Salons A, B, and C, 775 12th St. NW., Washington, DC.

Type of meeting and contact person. Open committee discussion, August 27, 1996, 8:15 a.m. to 3 p.m.; open public hearing, 3 p.m. to 5 p.m., unless participation does not last that long; open committee discussion, August 28, 1996, 8:15 a.m. to 4 p.m.; Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, or Catherine M. DeRoever (address above), Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Food Advisory Committee, code 10564. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee provides advice on emerging food safety, food science, and nutrition issues that FDA considers of primary importance in the next decade.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person by close of business August 21, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments. If necessary, comments may be limited to 5 minutes.

Open committee discussion. The Food Advisory Committee and the Ephedra Working Group will discuss the actions and recommendations made by the working group during its October 11 and 12, 1995, meeting. Additional information that has become available to FDA since that time will also be presented during the meeting. The committee will be asked to consider the original working group's recommendations in light of this new information.

Under 21 CFR 14.20 and 14.35, interested persons may submit written information or views on the matter(s) before the committee. Voluminous data are to be accompanied by a summary. Submissions must be made to the Executive Secretary and not directly to any committee members. Substantive submissions received at least 3 weeks prior to a meeting may be included in members' briefing materials; submissions received later will be distributed at the committee meeting. All submissions that include copyrighted materials must be accompanied by documented permission for duplication and distribution at no copyright expense to FDA.

At least 50 copies of each submission must be provided; sufficient additional copies may be requested by the agency for distribution to the public at a meeting. Fewer copies of voluminous submissions will be required; only summaries of such submissions will be provided to committee members, with complete copies of submissions being made available for circulation among committee members and for viewing by the public at a meeting.

More detailed information regarding the meeting agenda that may become available prior to the meeting will be provided to the public via the 800 number given above.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any