

[Docket No. 96F-0291]

**ICI Americas Inc.; Filing of Food Additive Petition****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that ICI Americas Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard intended for use in contact with food.

**DATES:** Written comments on the petitioner's environmental assessment by September 25, 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:** 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:** 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 6B4519) has been filed by ICI Americas Inc., 3411 Silverside Rd., Wilmington, DE 19850. The petition proposes to amend the food additive regulations to provide for the safe use of 12-hydroxystearic acid-polyethylene glycol (minimum MW 200) block copolymer as a surfactant in the manufacture of paper and paperboard intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before September 25, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office

above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, 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).

Dated: August 8, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval,  
Center for Food Safety and Applied Nutrition.  
[FR Doc. 96-21727 Filed 8-23-96; 8:45 am]

**BILLING CODE** 4160-01-F

**Advisory Committees; Notice of Meetings****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings 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.

**MEETINGS:** The following advisory committee meetings are announced:

**Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee**

*Date, time, and place.* September 20, 1996, 9:45 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-590-0044 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Shirley L. Meeks, Conference Management, 301-594-1283, ext. 113. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

*Type of meeting and contact person.* Closed committee deliberations, 9:45 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 4 p.m.; Michael G. Bazaral, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Anesthesiology and Respiratory Therapy Devices Panel, code 12624. Please call the hotline for information concerning any possible changes.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

*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 before September 12, 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.

*Open committee discussion.* The committee will hear presentations and public comment on the development of a guidance document for premarket notification submissions for continuous positive airway pressure devices for

treatment of obstructive sleep apnea. The panel will also hear presentations and public comment on the application of the rule exempting certain devices from premarket notification (510(k)) review (61 FR 1117, January 16, 1996), as related to anesthesiology and respiratory therapy devices.

**Closed committee deliberations.** FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

#### **Neurological Devices Panel of the Medical Devices Advisory Committee**

**Date, time, and place.** September 25, 1996, 9:30 a.m., Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Courtyard by Marriott, 2500 Research Blvd., Rockville, MD. Attendees requiring overnight accommodations may contact the hotel at 301-670-6700 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Shirley L. Meeks, Conference Management, 301-594-1283, ext. 113. The availability of appropriate accommodations cannot be assured unless prior notification is received.

**Type of meeting and contact person.** Open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 4 p.m.; closed committee deliberations, 4 p.m. to 5 p.m.; Jerilyn K. Glass, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Neurological Devices Panel, code 12513. Please call the hotline for information concerning any possible changes.

**General function of the committee.** The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

**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 before September 12, 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.

**Open committee discussion.** The committee will discuss and vote on a premarket approval application (PMA) for an implantable upper extremity functional neuroprosthetic device.

**Closed committee deliberations.** FDA staff will present to the committee trade secret and/or confidential commercial information regarding present and future FDA issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

#### **Hematology and Pathology Devices Panel of the Medical Devices Advisory Committee**

**Date, time, and place.** September 27, 1996, 9:30 a.m., Gaithersburg Hilton, Ballroom, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Hilton. Attendees requiring overnight accommodations may contact the hotel at 301-977-8900 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Joanne K. Choy, Conference Management, 301-594-1283, ext. 105. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

**Type of meeting and contact person.** Closed committee deliberations, 9:30 a.m. to 10 a.m.; open public hearing, 10 a.m. to 11:15 a.m., unless public participation does not last that long; open committee discussion, 11:15 a.m. to 6 p.m.; Djuana P. Blagmon, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Hematology and Pathology Devices Panel, code 12515. Please call the hotline for information concerning any possible changes.

**General function of the committee.** The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

**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 before September 13, 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.

**Open committee discussion.** The committee will discuss a PMA supplement for a computerized automated PAP smear reader that is indicated for use as a primary screener to select a subpopulation of smears that will be designated for no further review.

**Closed committee deliberations.** FDA staff will present to the committee trade secret and/or confidential commercial information regarding pending or future device submissions. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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 person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly

frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: August 19, 1996.  
Michael A. Friedman,  
Deputy Commissioner for Operations.  
[FR Doc. 96-21653 Filed 8-23-96; 8:45 am]  
BILLING CODE 4160-01-F

## **Health Care Financing Administration [R-187]**

### **Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and

Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Provider System (NPS); *Form No.:* HCFA-R-187; *Use:* HHS is consolidating provider enumeration across programs. The NPS will be used in program operations and management to assign provider identification numbers, i.e., billing numbers for claims processing and payment. It will replace the current Medicare Physician and Eligibility System (MPIES) and UPIN; it will replace the enumeration functions of the Medicare OSCAR, CLIA, and NSC provider numbering systems. *Frequency:* Annually; *Affected Public:* Federal Government, State, Local or Tribal Government, Individuals or Households, Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 88; *Total Annual Hours:* 23,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.