

Medical Devices Standards Activities Report (OMB Control Number 0910-0219—Extension)

FDA is collecting information necessary to update a comprehensive listing of current national and international standards activities in the field of medical devices. The collection of this information is authorized by section 514(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(a)(4)(B)), which requires FDA to consult with other nationally or

internationally recognized standard-setting entities, including other Federal agencies concerned with standard-setting, in carrying out its responsibility to establish special controls for medical devices. This report is used by approximately 39 standards-developing organizations to coordinate their standards activities. This coordination prevents duplication of effort and insures efficient and expeditious management of standards development. Over 700 copies of this report are used by government, hospitals, libraries,

industry, private citizens, and State and local government agencies, including FDA, to keep abreast of standards development activities and current technology concerning the safety of medical devices. Without the report, there would be duplication of standards efforts by voluntary standards organizations since there is no other publication that can be easily referenced to ascertain if a certain medical device standard is being or has been developed.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
39	.5	19.5	3	58.5

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

This collection occurs biennially and is voluntary. There are 39 national and international organizations with one report each reporting period.

Dated: October 29, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-28209 Filed 11-1-96; 8:45 am]

BILLING CODE 4160-01-F

the first column, in the first line, "[Docket No. 93F-0269]" is corrected to read "[Docket No. 93F-0273]".

Dated: October 16, 1996.

Alan M. Rulis,
Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
[FR Doc. 96-28210 Filed 11-1-96; 8:45 am]

BILLING CODE 4160-01-F

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:

Orthopedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. November 20, 1996, 10 a.m., and November 21, 1996, 8 a.m., Gaithersburg Hilton, Ballroom Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the Holiday Inn—Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301-948-8900 and reference FDA's Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Sue Bae, KRA Corp., 301-495-1591, ext. 227. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed committee deliberations, November 20, 1996, 10 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12:30 p.m., unless public participation does not last that long; open committee discussion, 12:30 p.m. to 6 p.m.; open committee discussion, November 21, 1996, 8 a.m. to 1:30 p.m.; Jodi H. Nashman, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036, or FDA Advisory Committee Information Hotline, 1-800-

[Docket No. 93F-0273]

Lonza, Inc.; Withdrawal of Food Additive Petition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of August 12, 1996 (61 FR 41793). The document announced the withdrawal 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. The document was published with an error. This document corrects that error.

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.

In FR Doc. 96-20437, appearing on page 41793 in the Federal Register of Monday, August 12, 1996, the following correction is made: On page 41793, in

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

741-8138 (301-443-0572 in the Washington, DC area), Orthopedic and Rehabilitation Devices Panel, code 12521. 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 November 8, 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. On the afternoon of November 20, 1996, and on the morning of November 21, 1996, the committee will discuss two separate premarket approval applications for sodium hyaluronates (also known as sodium hyaluronans and hyaluronic acid sodium salts) indicated for pain reduction and/or joint dysfunction in arthritic knees.

Closed committee deliberations. On November 20, 1996, 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)).

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 the meeting(s) 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: October 29, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-28207 Filed 11-1-96; 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:

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. November 19, 1996, 8 a.m., Gaithersburg Hilton, Ballroom Salons A, B, and C, 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 Gloria Williams, KRA Corp., 301-495-1591. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 12:30 p.m.; closed presentation of data, 12:30 p.m. to 1:30 p.m.; open committee discussion, 1:30 p.m. to 6 p.m.; Gail G. Gantt, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), General and Plastic Surgery Devices Panel, code 12519. 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 November 8, 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 general issues related to current breast biopsy devices. The committee will also discuss and vote on a premarket approval application (PMA) for a wound dressing for use in burns.

Closed presentation of data. The PMA sponsor may present to the committee trade secret and/or confidential commercial information regarding the wound dressing for burns. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

Date, time, and place. November 22, 1996, 8 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 Hotel—Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel

at 301-590-0044, or 1-800-228-9290 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 Alice Hall Hayes, KRA Corp., 301-495-1591, ext. 223. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Closed committee deliberations, 8 a.m. to 9:30 a.m.; 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.; 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 November 15, 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. A petition has been received for reclassification of a nitric oxide administration system. The committee will discuss the reclassification from class III into class II of a system for nitric oxide administration. As part of the discussion, the committee will discuss three new devices: (1) A nitric oxide administration device; (2) a device to monitor nitric oxide gas concentration in the administration system during the administration of nitric oxide; and (3) a device to monitor nitrogen dioxide gas concentration in the administration system during the administration of nitric oxide.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial