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FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of May 9, 1996 (61 FR 21193), FDA announced that a food additive petition (FAP 6A4499) had been filed by Bio-Cide International, Inc., 2845 Broce Dr., Norman, OK 73072. The petition proposed to amend the food additive regulations in part 173 *Secondary Direct Food Additives Permitted in Food for Human Consumption* (21 CFR part 173) to provide for the safe use of acidified sodium chlorite solutions in processing water and ice which directly contact seafood such as finfish, shellfish, and crustaceans for the control of naturally occurring spoilage microorganisms to increase shelf life and to enhance seafood product freshness. Bio-Cide International, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: November 6, 1996.

Alan M. Rulis,

Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
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Advisory Committee; 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:

Blood Products Advisory Committee

Date, time, and place. December 12 and 13, 1996, 1 a.m., Holiday Inn—Bethesda, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open committee discussion, December 12, 1996, 8 a.m. to 10:30 a.m.; open public hearing, 10:30 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 12:15 p.m.; open public hearing, 12:15 p.m. to 12:30 p.m., unless public participation does not last that long; open committee discussion, 12:30 p.m. to 3 p.m.; open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 5:30 p.m.; open committee discussion, December 13, 1996, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 11:30 a.m.; open public hearing, 11:30 a.m. to 12 m., unless public participation does not last that long; open committee discussion, 12 m. to 12:30 p.m.; closed committee deliberations, 12:30 p.m. to 1 p.m.; open committee discussion, 1 p.m. to 2:30 p.m.; open public hearing, 2:30 p.m. to 3 p.m., unless public participation does not last that long; open committee discussion, 3 p.m. to 3:30 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Blood Products Advisory Committee, code 12388. 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, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

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 December 6, 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 morning of December 12, 1996, the

committee will discuss the status of review of recombinant Factor IX, BeneFIX, Genetics Institutes, and review the FDA proposal on limiting plasma pool size for fractionated plasma products. In the afternoon, the committee will review issues of safety and efficacy concerning solvent detergent plasma, New York Blood Center. On the morning of December 13, 1996, the committee will review the status of HTLV-I/HTLV-II EIA, Abbott Laboratories, as in vitro diagnostic test kit to screen blood donors for the human tlymphotropic virus Types I and II, and the use of external controls with licensed infectious disease diagnostic test kits used for blood donor screening. In the afternoon, the committee will hear an informational report on the reinvention of the biologics license application (BLA) for blood products.

Closed committee deliberations. On the afternoon of December 13, 1996, the committee may review trade secret and/or confidential commercial information relevant to current and pending products. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. December 20, 1996, 9 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 800-228-9290 or 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 Michelle Healy, KRA Corp. 301-495-1591. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Closed committee deliberations, 9 a.m. to 10 a.m.; open public hearing, 10 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 1 p.m.; closed presentation of data, 1 p.m. to 2 p.m.; open committee discussion, 2 p.m. to 5 p.m.; Cornelia B. Rooks, 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), Clinical Chemistry and Clinical Toxicology Devices Panel, code 12514. Please call the hotline for information concerning any possible change.

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 December 1, 1996, to 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 consider a premarket approval application (PMA) for a device which calculates a composite index from currently available serum-based clinical laboratory tests to provide additional information, which can assist in identifying osteopenia in women with three or more National Osteoporosis Foundation Risk Factors.

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)).

Closed presentation of data. The sponsor of the PMA will present to the committee trade secret and/or confidential information. 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: November 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

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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