Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC, Attn: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, 107.280 (OMB Control Number 0910–0188—Reinstatement)

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to evaluate the hazard to human health, devise a written recall strategy, promptly notify each affected direct account (customer) about the recall, and furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described above are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA's ability to ensure that recalls are conducted properly would be greatly impaired.

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

ESTIMATED ANNUAL REPORTING BURDEN

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 107.230 | 0.5 | 1 | 0.5 | 4,500 | 2,250 |
| 107.240 | 0.5 | 1 | 0.5 | 1,482 | 741 |
| 107.250 | 0.5 | 1 | 0.5 | 120 | 60 |
| 107.260 | 0.5 | 1 | 0.5 | 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: November 15, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–29945 Filed 11–21–96; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 96F–0139]**

## Bio-Cide International, 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 future filing, of a food additive petition (FAP 6A4499) proposing that the food additive regulations be amended 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.

**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.*

[FR Doc. 96–29829 Filed 11–21–96; 8:45 am]

**BILLING CODE 4160–01–F**

## 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–1/HTLV–II EIA, Abbott Laboratories, as in vitro dragnostic 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)).

Clincal 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