

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Decision To Evaluate a Petition To Designate a Class of Employees From the Battelle Laboratories King Avenue Facility in Columbus, OH, To Be Included in the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: NIOSH gives notice as required by 42 CFR 83.12(e) of a decision to evaluate a petition to designate a class of employees from the Battelle Laboratories King Avenue facility in Columbus, OH, to be included in the Special Exposure Cohort under the Energy Employees Occupational Illness Compensation Program Act of 2000. The initial proposed definition for the class being evaluated, subject to revision as warranted by the evaluation, is as follows:

Facility: Battelle Laboratories King Avenue Location: Columbus, Ohio.

Job Titles and/or Job Duties: All Atomic Weapons Employees who worked at the King Avenue facility in Columbus, Ohio.

Period of Employment: April 16, 1943 through June 30, 1956.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C-46, Cincinnati, OH 45226, Telephone 877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

John Howard,

Director, National Institute for Occupational Safety and Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0848]

Draft Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft Compliance Policy Guide entitled “Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin (the draft CPG).” The draft CPG, when finalized, will provide guidance for FDA staff on our enforcement criteria for canned ackee, frozen ackee, and other ackee products that contain hypoglycin A.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on the draft CPG before it begins work on the final version of the CPG, submit electronic or written comments on the draft CPG by January 7, 2013.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240-632-6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

Submit electronic comments on the draft CPG to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Yinqing Ma, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1700.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the draft CPG entitled “Compliance Policy Guide Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin.” The draft CPG is intended to provide guidance for FDA staff regarding hypoglycin A in canned ackee, frozen ackee, and other ackee products. We have concluded that canned ackee, frozen ackee, and other ackee products containing concentrations of hypoglycin A above 100 parts per million (ppm) have not been processed properly, and that the finished product may be injurious to health. As stated in the draft CPG, canned ackee, frozen ackee, and other ackee products may be considered adulterated within the meaning of section 402(a)(4) of the Federal Food,

and Cosmetic Act (21 U.S.C. 342(a)(4)) when hypoglycin A is present in the food at levels greater than 100 ppm. The draft CPG also contains information that may be useful to the regulated industry and to the public.

The draft CPG is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent our current thinking on hypoglycin A in ackee products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding the draft CPG to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG either from FDA’s Office of Regulatory Affairs history page at http://www.fda.gov/ora/compliance_ref/cpg/default.htm or from <http://www.regulations.gov>. Always access an FDA guidance document by using FDA’s Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-27225 Filed 11-7-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee

of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 4, 2012, from 12 noon to 5:30 p.m. and on December 5, 2012, from 8 a.m. to 4:30 p.m.

Location: 5630 Fishers Lane, FDA Conference Room 1066, Rockville, MD 20857. For those unable to attend in person, the meeting will also be Webcast. The Webcast will be available at the following links:

December 4, 2012: Blood Products Advisory Committee Day 1: <http://fda.yorkcast.com/webcast/Viewer/?peid=fea7b950961349e88d443de17679b20c1d>.

December 5, 2012: Blood Products Advisory Committee Day 2: <http://fda.yorkcast.com/webcast/Viewer/?peid=9528ed4e66ca4fbb862be35598b621321d>.

Contact Person: Bryan Emery or Pearlina Muckelvene, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1277 or 301-827-1281, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On December 4, 2012, the Committee will meet in open session to discuss labeling of Red Blood Cells with historical antigen typing results. On December 5, 2012, the Committee will meet in open session to discuss performance data considerations for infectious disease assays used to screen organ donors.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the

location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 27, 2012. On December 4, oral presentations from the public will be scheduled between approximately 3 p.m. and 4 p.m. On December 5, oral presentations will be scheduled between approximately 11:20 a.m. and 12:20 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 requested to make their presentation on or before November 19, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 20, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. Seating for this meeting may be limited, so the public is encouraged to watch the free Webcast if you are unable to attend. The link for the Webcast will be available at 8 a.m. on December 4 and 5, 2012 (see *Location*).

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 5, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012-27323 Filed 11-7-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: December 4, 2012, 8:30 a.m. to 5:00 p.m.

December 5, 2012, 8:00 a.m. to 12:00 p.m.

Place: Health Resources and Services Administration, 5600 Fishers Lane, Room 18-67, Rockville, Maryland 20857, Telephone: (301) 594-4303, Fax: (301) 443-0248.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal agricultural workers and their families and to formulate recommendations for the Secretary of Health and Human Services.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on agricultural worker issues, including the status of agricultural workers' health at the local and national levels.

Agenda items are subject to change as priorities indicate.

FOR FURTHER INFORMATION CONTACT:

Gladys Cate, Office of Special Population Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Room 15-74, Rockville, Maryland 20857; telephone (301) 594-0367.

Dated: October 31, 2012.

Wendy Ponton,

Director, Office of Management.

[FR Doc. 2012-27312 Filed 11-7-12; 8:45 am]

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