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, Drug, 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.

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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