ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
General public; specifically targeting external governmental and non-governmental organizations including non-profit organizations, trade associations, academic and research institutions, and the private sector.	Become a Partner	100	1	15/60
General public; specifically targeting external governmental and non-governmental organizations including non-profit organizations, trade associations, academic and research institutions, and the private sector.	Become a Partner Follow-Up Questions.	100	1	30/60

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–08446 Filed 4–14–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0848]

Compliance Policy Guide Regarding 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 the Compliance Policy Guide (CPG) Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin. The CPG provides guidance for FDA staff on our enforcement criteria for canned ackee, frozen ackee, and other ackee products that contain hypoglycin A.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Office of Policy and Risk Management, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, 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 301–827–3670. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the 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 CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin. The CPG is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The CPG represents our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of November 8, 2012 (77 FR 67013), we announced the availability of draft CPG Sec. 550.050 Canned Ackee, Frozen Ackee, and Other Ackee Products—Hypoglycin A Toxin and gave interested parties an opportunity to submit comments by January 7, 2013, for us to consider before beginning work on the final version of the CPG. We received one comment that did not pertain to the draft CPG. We are issuing the final version of the CPG with editorial changes, but with no substantive changes.

The CPG announced in this notice finalizes the draft CPG dated November 2012.

II. Comments

Interested persons may submit either written comments regarding the CPG to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding the CPG 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 CPG from FDA's Office of Regulatory Affairs CPG history page at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or from *http://www.regulations.gov*. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: April 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08428 Filed 4–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: NIMH Database of Cognitive Training and Remediation Studies (DCTRS) (NIMH)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Mental Health (NIMH), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *kshropsh@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: NIMH Database of Cognitive Training and Remediation Studies, 0925–New; National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: The NIMH Database of Cognitive Training and Remediation Studies (DCTRS) is an integrated database that includes study- and subject-level data from studies of cognitive remediation (CR) in schizophrenia. DCTRS will allow NIMH staff and interested investigators to examine the ways in which various patient characteristics, intervention approaches and features, and treatment combinations affect responses to remediation. The DCTRS Study Information Form and Data Submission Agreement are necessary for the ''Submitter'' to request permission to submit study data to the NIMH DCTRS for general research purposes. The primary use of this information is to collect submitter information and study information for inclusion in the NIMH DCTRS database. The DCTRS data submission agreement includes two forms: (1) The data submission form that includes the terms, agreement, submitter information and certifications, and (2) the study information form which collects de-identified data for each study.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 60.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Frequency of response	Average time per response (in hours)	Annual hour burden
Data Submission Agreement	Principal Investigators/Physicians	12	1	5	60

Dated: April 7, 2014.

Keisha L Shropshire,

Project Clearance Liaison, NIMH, NIH.

[FR Doc. 2014–08533 Filed 4–14–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Option License: Immunotherapy Vaccine for Treating Lymphoma and Leukemia

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant to University of Texas MD Anderson Cancer Center, of an exclusive option license to practice the inventions embodied in the following US Patents and US Patent Applications (and all foreign counterparts) for the continued research and development of the inventions: US Patent Application Serial No. 13/890,502, entitled, ''Viral Chemokine-antigen Fusion Proteins'' [HHS Ref. No. E–194–2000/0–US–06] and in US Patent Serial No. 8,258,278 and US Patent Application Serial No.13/587,515, both entitled ''Methods and Compositions for the Treatment and Prevention of Cancer'' [HHS Ref. Nos. E–271–2006/0–US–03 and E–271–2006/0–US–04, respectively]. The patent rights in this invention have been assigned to the Government of the United States of America.

The exclusive option license may be term-limited, the prospective territory may be worldwide, and the field of use may be limited to:

Research, development, manufacture, and related non-commercial use in humans for the treatment of B-cell leukemias and B-cell lymphoma of a chemokine-tumor antigen fusion protein in which the chemokine is viral Macrophage Inflammatory Protein 3 Alpha (MIP3α) and the tumor antigen is the epitope of a malignant B-cell immunoglobulin idiotype of an antibody produced by a B-cell lymphoma.

Prior to the expiration or termination of the exclusive option license, University of Texas M.D. Anderson Cancer Center will have the exclusive right to amend the option license to include the right to sublicense for commercialization.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before April 30, 2014 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive option license should be directed to: Yolanda Mock Hawkins, Ph.D., M.B.A., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5170; Facsimile: (301) 402–0220; Email: *hawkinsy@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: This invention concerns a cancer treatment for B-cell lymphoma comprising a vaccine that increases the ability of a B-cell lymphoma antigen to provoke an immune response in the body. In particular, the vaccine comprises a viral chemokine fused to a tumor antigen and