communicating with us about the safety evaluation.

Interested persons may use Form FDA 3666 to transmit their submissions to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition. Form FDA 3666 is entitled ''Early Food Safety Evaluation of a New Non-Pesticidal Protein Produced by a New Plant Variety (New Protein Consultation)'' (*https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM350010.pdf*) and may be used in lieu of a cover letter for a New Protein Consultation (NPC). Form FDA 3666 prompts a submitter to include certain elements of a NPC in a standard format and helps the respondent organize their submission to focus on the information needed for our safety review. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submission Gateway (*https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm*), paper format, or as electronic files on physical media with a paper signature page. FDA uses this information to evaluate the food safety of a specific new protein produced by a new plant variety.

Description of Respondents: The respondents to this collection of information are developers of new plant varieties intended for food use.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
First four data components	3666	6	1	6	4	24
Two other data components	3666	6	1	6	16	96
Total						120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. The estimated number of annual responses and average burden per response are based on our experience with early food safety evaluations. Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted in such a way (*e.g.,* on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with us about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

We estimate the annual number of NPCs submitted by developers will be six or fewer. The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. We estimate that completing these data components will take about 4 hours per NPC. We estimate the reporting burden for the first four data components to be 24 hours (4 hours × 6 responses).

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis that can be performed using publicly available databases. The other data component involves ''wet'' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study). The paperwork burden of these two data components consists of the time it takes the company to assemble the information on these two data components and include it in a NPC. We estimate that completing these data components will take about 16 hours per NPC. We estimate the reporting burden for the two other data components to be 96 hours (16 hours × 6 responses). Thus, we estimate the total annual burden for this collection of information to be 120 hours.

Dated: May 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–11281 Filed 5–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Commission on Childhood Vaccines

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Advisory Committee meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold a public meeting. This meeting will be open to the public.

DATES: Friday, June 15, 2018, from 10:00 a.m. to 2:00 p.m. ET.

ADDRESSES: The meeting is a teleconference and webinar. The conference call-in number is 1–800–988–0218; passcode: 9302948. The webinar link is *https://hrsa.connectsolutions.com/accv/.* Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.*

FOR FURTHER INFORMATION CONTACT: Annie Herzog, Principal Staff Liaison, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; phone: (301) 443–6593; or email: *aherzog@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The ACCV advises the Secretary on the implementation of the Vaccine Injury Compensation Program (VICP). Other activities of the ACCV include: Recommending changes to the Vaccine Injury table, at its own initiative or as the result of the filing of a petition; advising the Secretary on implementing section 2127 of the Public Health Service Act (PHS Act) regarding

the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying federal, state, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125 (b) of the PHS Act; advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; consulting on the development or revision of Vaccine Information Statements; and recommending to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the VICP.

Agenda: During the June 15, 2018, meeting, agenda items may include updates from DICP, Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). Information about the ACCV, a roster of members, the meeting agenda, as well as past meeting summaries, is located on the ACCV website: *http://www.hrsa.gov/advisorycommittees/childhoodvaccines/index.html.* Agenda items are subject to change as priorities dictate.

Public Participation: Members of the public will have the opportunity to provide comments. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to make oral comments or provide written comments to the ACCV should be sent to Annie Herzog by June 5, 2018. Individuals who plan to participate and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Annie Herzog, using the address and phone number above at least 10 days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–11298 Filed 5–24–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the CLINICAL CENTER, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center Board meeting.

Date: June 15, 2018.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate reports and responses to the following Clinic Center's Departments: Rehabilitation Medicine, Bioethics, Critical Care Medicine, Imaging Sciences, Transfusion Medicine, Laboratory Medicine, Nursing, and Pediatrics.

Place: National Institutes of Health, Building 10, 10 Center Drive, Bethesda, MD 20892.

Contact Person: John I. Gallin, M.D., Associate Director for Clinical Research, Office of Director, NIH Clinical Center, 1 Center Drive, Room 201, Bethesda, MD 20892, 301–827–5428.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: May 18, 2018.

Michelle D. Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–11212 Filed 5–24–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

AGENCY: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Summary Information section of this notice to to Fundacao Butantan, having a place of business in Sao Paulo, Brazil.

DATES: Only written comments and/or application for a license which are received by the NIAID Technology Transfer and Intellectual Property Office on or before June 25, 2018 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated Exclusive Commercialization Patent License should be directed to: Peter Soukas, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Suite 6D, Rockville, MD 20852–9804; Email: *ps193c@nih.gov;* Telephone: (301) 496–2644; Facsimile: (240) 627–3117.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application Number 62/307,170, filed March 11, 2016 and entitled ''Live Attenuated Zika Virus Vaccines,'' Whitehead et al., and PCT Patent Application Number PCT/US2017/0021989, filed March 11, 2017 and entitled ''Live Attenuated Zika Virus Vaccines,'' Whitehead et al. [HHS Reference E–118–2016/0]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned to the government of the United States of America.