''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David McMillan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6387, Silver Spring, MD 20993, 240–402–1009; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics.'' This guidance provides consistent recommendations for the nonclinical assessments of immune endpoints and supplements the recommendations provided in other guidances, most notably the ICH guidance for industry ''S8 Immunotoxicity Studies for Human Pharmaceuticals.'' This guidance replaces the withdrawn guidance entitled ''Immunotoxicology Evaluation of Investigational New Drugs'' issued November 1, 2002 (67 FR 66647). The topics addressed include multiple aspects of immune suppression, modulation, and stimulation, including carcinogenicity assessment, dermal sensitization, adjuvanted vaccine development, and developmental and juvenile animal studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Nonclinical Safety Evaluation of the Immunotoxic Potential of Drugs and Biologics.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The information collection has been approved under OMB control numbers 0910–0001 and 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: February 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03426 Filed 2–19–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

HHS Notice of Committee Establishment, Notice of Intent To Convene, and Call for Nominations for the NIH Human Fetal Tissue Research Ethics Advisory Board for Fiscal Year 2020

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the establishment of, and intent to convene, the National Institutes of Health (NIH) Human Fetal Tissue Research Ethics Advisory Board—FY 2020 (Ethics Board or Board), as authorized by section 492A of the Public Health Service (PHS) Act, as amended. HHS is soliciting nominations of individuals for appointment to the Ethics Board for fiscal year 2020. Nominations for qualified individuals for appointment to the Ethics Board are currently being accepted.

DATES: Nominations must be received no later than 5:00 p.m. ET 30 days after the publication of this **Federal Register** notice.

ADDRESSES: Nomination packages must be submitted to the Executive Secretary, NIH Human Fetal Tissue Research Ethics Advisory Board—FY 2020, Office of Science Policy, NIH, 6705 Rockledge Drive, Suite 750 Bethesda, MD 20892. Federal Express, Airborne, UPS, etc., mail delivery should be addressed to Executive Secretary, NIH Human Fetal Tissue Research Ethics Advisory Board—FY 2020, Office of Science Policy, NIH, at the above address, or sent via email to: *SciencePolicy@od.nih.gov*

FOR FURTHER INFORMATION CONTACT: Inquiries may be directed to Cari Young, Office of Science Policy, 6705 Rockledge Drive, Suite 750 Bethesda, MD 20892, Telephone: 301–496–9838, or *SciencePolicy@od.nih.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to section 492A of the Public Health Service (PHS) Act, 42 U.S.C. 289a–1, as amended, and in accordance with the policy announced on June 5, 2019, the Secretary announces (1) his

determination that an advisory board should be convened to recommend whether, with respect to research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, described in the NIH Guide Notice NOT–OD–19–128, the Secretary should withhold funds or not withhold funds because of ethical considerations; (2) his intent to convene such an advisory board; and (3) the establishment of the NIH Human Fetal Tissue Ethics Advisory Board—FY 2020. NIH Human Fetal Tissue Ethics Advisory Board—FY 2020 is governed by the Federal Advisory Committee Act (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The number of meetings to be held by the Board will depend on the number of relevant NIH grant and cooperative agreement applications and R&D contract proposals pending the Board's consideration. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public.

In accordance with section 492A(5)(B)(ii) of the PHS Act, no later than 180 days after the date on which this notice is published in the **Federal Register**, the Board will submit to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report describing the findings of the Board regarding the project(s) of research involved and recommendations regarding whether the Secretary should or should not withhold funds for the project(s). As required by section 492A(b)(5)(K) of the PHS Act, the Ethics Board will terminate 30 days after the date on which the required report is submitted to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate.

Notice of Establishment: Pursuant to the Federal Advisory Committee Act, as amended (5 U.S.C. App.), the Secretary of Health and Human Services (HHS), announces the establishment of the NIH Human Fetal Tissue Research Ethics Advisory Board—FY 2020, as authorized by section 492A of the Public Health Service (PHS) Act, 42 U.S.C. 289a–1, as amended.

The Ethics Board will advise, consult with, and make recommendations to, the Secretary of Health and Human Services (Secretary) regarding the ethics of research involving human fetal tissue (HFT) proposed in NIH grant and cooperative agreement applications and R&D contract proposals, described in the NIH Guide Notice NOT–OD–19–128. Recommendations will address whether the Secretary should withhold funds or not withhold funds from a proposed project because of ethical considerations. In providing advice and recommendations on these matters, the Ethics Board will consider, among other things, the use of alternative models, and review and verify the core ethical principles and procedures used in the process to obtain written voluntary informed consent for the donation of the tissue. The ethical considerations the Ethics Board should consider are those related to whether the nature of the research involved is such that it is unethical to conduct or support the research.

Notice of Intent To Convene: Consistent with section 492A of the PHS Act, this announcement outlines the intention of the HHS Secretary to convene the Ethics Board and solicits nominations for the individuals who should be considered for appointment to the Board. The Secretary will consider such recommendations in making appointments to the Board.

Call for Nominations: The Board will be composed of 15 individuals who are not federal employees. Section 492A(b)(5)(C) of the PHS Act establishes certain requirements for the composition of the Board. The appointed members of the Board will include no fewer than one attorney; no fewer than one ethicist; no fewer than one practicing physician; and no fewer than one theologian. No fewer than one-third, and no more than one-half of the appointed members will be scientists with substantial accomplishments in biomedical or behavioral research.

Interested individuals may self-nominate or be nominated by another individual or organization. The following information may be included in the package of materials submitted for each individual being nominated for consideration: (1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.,* the specific attributes, perspectives, and/or skills the individual possesses that would benefit the workings of the Ethics Board), and the nominee's field(s) of expertise; (2) a biographical sketch of the nominee; (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted; (4) a current copy of the nominee's curriculum vitae; and (5) the category of Board member the nominee would fill (*i.e.,* attorney, ethicist, practicing physician, theologian, or scientist with substantial accomplishments in biomedical or behavioral research). Nomination packages may be submitted directly by the individual being nominated or by the person/organization recommending the candidate.

Dated: February 12, 2020.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–03302 Filed 2–19–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; ZAI1–EC–D–M1, NIAID Research Education Program (R25) Mar 31, 2020.

Date: March 31, 2020.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Eleazar Cohen, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institute of Health, 5601 Fishers Lane, Room 3G62A, Bethesda, MD 20892, (240) 669–5081, *ecohen@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)