1271; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''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.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, 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 document entitled ''Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271; Guidance for Industry.'' The document provides establishments that manufacture HCT/Ps, regulated solely under section 361 of the PHS Act and the regulations under 21 CFR part 1271, with recommendations and relevant examples for complying with the requirements under 21 CFR 1271.350(b) to investigate and report HCT/P deviations. The examples provided in the guidance are intended to illustrate those HCT/P deviations that have been most frequently reported to FDA, CBER.

The guidance does not apply to reproductive HCT/Ps or to HCT/Ps regulated under 21 CFR part 1270 and recovered before May 25, 2005. The guidance does not apply to healthcare professionals who implant, transplant, infuse, or transfer HCT/Ps into recipients. The guidance also does not apply to HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, nor does it apply to investigational HCT/Ps subject to an investigational new drug application or an investigational device exemption.

In the **Federal Register** of December 24, 2015 (80 FR 80364), FDA announced the availability of the draft guidance of the same title dated December 2015. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes additional examples and editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2015.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under section 361 of the Public Health Service Act and 21 CFR part 1271.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3520). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: August 23, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–18737 Filed 9–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Listing of Members of the National Institutes of Health's Senior Executive Service 2017 Performance Review Board (PRB)

SUMMARY: The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health's Senior Executive Service 2017 Performance Review Board.

FOR FURTHER INFORMATION CONTACT: For further information about the NIH Performance Review Board, contact the Office of Human Resources, Division of Senior and Scientific Executive Management, National Institutes of Health, Building 2, Room 5E18, Bethesda, Maryland 20892, telephone 301–402–7999 (not a toll-free number).

SUPPLEMENTARY INFORMATION: This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure

consistency, stability, and objectivity in performance appraisals and requires that notice of the appointment of an individual to serve as a member be published in the **Federal Register.**

The following persons will serve on the NIH Performance Review Board, which oversees the evaluation of performance appraisals of NIH Senior Executive Service (SES) members:

Alfred Johnson, Chair
Joellen Austin
Michael Gottesman
Richard Ikeda
Michael Lauer
Ellen Rolfes
LaVerne Stringfield
Lawrence Tabak
Timothy Wheeles

Dated: August 30, 2017.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2017–18899 Filed 9–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council for Complementary and Integrative Health

Date: October 6, 2017

Closed: 8:30 a.m. to 9:45 a.m.

Agenda: To review and evaluate grant applications

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: A report from the Institute Director and other staff.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Partap Singh Khalsa, Ph.D., DC, Director, Division of Extramural Activities, National Center for Complementary and Integrative Health, NIH, National Institutes of Health, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892–5475, (301) 594–3462, *khalsap@mail.nih.gov.*

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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://nccih.nih.gov/about/naccih/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: August 31, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–18897 Filed 9–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[CBP Dec. 17–11]

Western Hemisphere Travel Initiative: Designation of an Approved Native American Tribal Card Issued by the Pokagon Band of Potawatomi Indians as an Acceptable Document To Denote Identity and Citizenship for Entry in the United States at Land and Sea Ports of Entry

AGENCY: U.S. Customs and Border Protection; DHS.

ACTION: Notice.

SUMMARY: This notice announces that the Commissioner of U.S. Customs and Border Protection is designating an approved Native American Tribal Card issued by the Pokagon Band of Potawatomi Indians (Pokagon Band) to U.S. and Canadian citizens as an acceptable travel document for purposes of the Western Hemisphere Travel Initiative. The approved card may be used to denote identity and citizenship of Pokagon Band members entering the United States from contiguous territory or adjacent islands at land and sea ports of entry.

DATES: This designation will become effective on September 7, 2017.

FOR FURTHER INFORMATION CONTACT: Colleen Manaher, Executive Director, Planning, Program Analysis, and Evaluation, Office of Field Operations, U.S. Customs and Border Protection, via email at *Colleen.M.Manaher@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Western Hemisphere Travel Initiative

Section 7209 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Public Law 108–458, as amended, required the Secretary of Homeland Security (Secretary), in consultation with the Secretary of State, to develop and implement a plan to require U.S. citizens and individuals for whom documentation requirements have previously been waived under section 212(d)(4)(B) of the Immigration and Nationality Act (8 U.S.C. 1182(d)(4)(B)) to present a passport or other document or combination of documents as the Secretary deems sufficient to denote identity and citizenship for all travel into the United States. *See* 8 U.S.C. 1185 note. On April 3, 2008, the Department of Homeland Security (DHS) and the Department of State promulgated a joint final rule, effective on June 1, 2009, that implemented the plan known as the Western Hemisphere Travel Initiative (WHTI) at U.S. land and sea ports of entry. *See* 73 FR 18384 (the WHTI Land and Sea Final Rule). It amended various sections of the Code of Federal Regulations (CFR), including 8 CFR 212.0, 212.1, and 235.1. The WHTI Land and Sea Final Rule specifies the documents that U.S. citizens and nonimmigrant aliens from Canada, Bermuda, and Mexico are required to present when entering the United States at land and sea ports of entry.

Under the WHTI Land and Sea Final Rule, one type of citizenship and identity document that may be presented upon entry to the United