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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, AUSTEDO (deutetrabenazine) indicated for treatment of chorea associated with Huntington's disease. Subsequent to this approval, the USPTO received a patent term restoration application for AUSTEDO (U.S. Patent No. 8,524,733) from Auspex Pharmaceuticals, Inc. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated February 2, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AUSTEDO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for AUSTEDO is 1,736 days. Of this time, 1,060 days occurred during the testing phase of the regulatory review period, while 676 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 3, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was July 3, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* May 29, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for AUSTEDO (NDA 208082) was initially submitted on May 29, 2015.

3. *The date the application was approved:* April 3, 2017. FDA has verified the applicant's claim that NDA 208082 was approved on April 3, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 8 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09805 Filed 5–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Testing Services and Scores for Foreign Health Care Workers To Demonstrate English Language Proficiency

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

ACTION: Request for comments; notice of public meeting.

SUMMARY: HRSA announces a request for comments and notice of a public meeting to receive feedback on proposed updates to the list of testing services and scores for foreign health care workers to demonstrate English language proficiency pursuant to section 343 of the Illegal Immigration Reform

and Immigrant Responsibility Act of 1996 (IIRIRA).

DATES:

- The public meeting will be held on May 28, 2019, 1:00 p.m.–4:00 p.m. ET.
- Comments should be submitted by June 11, 2019, 11:59 p.m. ET.

ADDRESSES: The public may attend the public meeting via teleconference and in-person. The conference call-in number is (888) 455–4758; Participant Passcode is 3016308. The address for the public meeting is 5600 Fishers Lane, Room 5N54, Rockville, Maryland 20857.

Comments should be sent to *HRSAComments@hrsa.gov* with the subject line: ''Testing Services and Scores for Foreign Health Care Workers''.

FOR FURTHER INFORMATION CONTACT: LCDR Charlie Darr, Office of Global Health, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; via email: *OGHpublicmeeting@hrsa.gov;* or phone: (301) 443–2741.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this request for comments and notice of public meeting is to elicit stakeholder feedback to HRSA regarding its proposed updates to the list of approved testing services and passing scores pursuant to section 343 of the IIRIRA and implementing regulations promulgated by the Department of Homeland Security (DHS). Specifically, HRSA is seeking comments regarding the current and proposed list of approved standardized tests and passing scores, required for certification of foreign health care workers seeking to demonstrate English language proficiency under section 343 of the IIRIRA and implementing regulations.

Under the authority of section 343 of IIRIRA, Public Law 104–208 (8 U.S.C. 1182(a)(5)(C)), as implemented by the Department of Homeland Security (DHS) at 8 CFR 212.15(g), standards for these English language requirements, as shown by an appropriate minimum score on one or more nationally recognized, commercially available, standardized assessments of the applicant's ability to speak and write, are set by the Secretary of HHS. Demonstration of English language proficiency is an element of the certification requirements for foreign health care workers seeking admission to the United States for the primary purpose of performing labor in a covered health care occupation. DHS implementing regulations authorize HHS to notify DHS of additions and deletions to the approved list of testing services and scores.

HRSA, under authority delegated by HHS, reviews and evaluates studies and other supporting materials presented to evaluate English language proficiency tests and language scoring level for the health occupations described in 8 CFR 212.15. Accordingly, HRSA is seeking public comment on proposed additions and deletions to the list of testing services and passing scores, including comments that address studies, methodologies, and analysis of such tests and passing scores.

Below is a Description of the HRSA-Proposed Updates to the Tests Listed in the Regulation at 8 CFR 212.15

HRSA is not proposing changes to the current standardized tests and scores for the following tests listed in the DHS regulation:

- Paper-delivered version of the Electronic Testing Service (ETS), Test of English as a Foreign Language (TOEFL-Paper-delivered Test);
- Test of English in International Communication (TOEIC); and
- International English Language Testing System

HRSA is proposing to add the following standardized tests (with indicated passing scores) to the tests currently listed in the DHS regulation:

- Internet-based version of the ETS TOEFL Test

The ETS TOEFL test, delivered via the internet, measures the test-taker's ability to use and understand English by evaluating combined reading, listening, speaking, and writing skills. Each section of the test (Reading, Listening, Speaking, and Writing) has a maximum score of 30 points, with a maximum total score of 120 points. The proposed overall passing score for occupational therapists and physical therapists is 89, including an aggregate minimum score of 63 on the Reading, Listening, and Writing sections, and a minimum score of 26 on the Speaking section. The proposed overall passing score for registered nurses and other foreign-educated health care workers whose occupations require attainment of a baccalaureate degree is 81, including an aggregate minimum score of 57 on the Reading, Listening, and Writing sections, and a minimum score of 24 on the Speaking section. The proposed overall passing score for occupations requiring less than a baccalaureate degree is 77, including an aggregate minimum score of 53 on the Reading, Listening, and Writing sections, and a minimum score of 24 on the Speaking section.

- TOEIC Speaking and Writing Tests

ETS has eliminated the Test of Spoken English and the Test of Written English from its currently available offerings and added the TOEIC Speaking Test and Writing Tests. Both the TOEIC Speaking and Writing tests are scored on a scale of 0–200. HRSA proposes a passing score of 160 on the TOEIC Speaking Test and 150 on the TOEIC Writing Test for registered nurses and other health care occupations requiring attainment of a baccalaureate degree, in addition to passing scores on the TOEIC test measuring Listening and Reading comprehension (passing score of 725 remains unchanged from current IIRIRA regulations). For health care occupations requiring less than a baccalaureate degree, HRSA proposes a passing score of 160 on the TOEIC Speaking Test and 150 on the TOEIC Writing Test; in addition to passing scores on the TOEIC test measuring Listening and Reading comprehension (passing score of 700 remains unchanged from current IIRIRA regulations).

- Pearson Test of English Academic (PTE Academic)

PTE Academic is a computer-based, internationally recognized, commercially available, standardized assessment of written and spoken English that measures the reading, writing, listening, and speaking abilities of test takers. The test includes an overall score (the Global Scale of English) that ranges from 10–90 and shows the overall English academic language ability of a test taker. Each test assesses an individual's communicative and enabling skills in sections (listening, reading, speaking, writing, grammar oral fluency, pronunciation, spelling, vocabulary, and written discourse) from a range of 10–90. HRSA proposes to add PTE Academic to the list of approved tests for registered nurses and other health care occupations requiring attainment of a baccalaureate degree, and for health care occupations requiring less than a baccalaureate degree. HRSA proposes a passing score of 55 with no individual communicative or enabling skills score below 50.

HRSA is proposing to delete the following standardized tests (which are no longer in use) from the tests currently listed in the DHS regulation:

- *ETS:* Test of Spoken English and Test of Written English—Eliminated from the current available offerings by ETS.
- TOEFL Computer-based Test—Discontinued by ETS.

II. Format

Request for Comment: Comments should be submitted to HRSA by June 11, 2019, 11:59 p.m. ET. Email comments to *HRSAComments@hrsa.gov* with the subject line: ''Testing Services and Scores for Foreign Health Care Workers''.

Public Meeting: This meeting is open to the public. Attendance can be by teleconference or in person. To register for either the teleconference or in person attendance, please provide complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and indicate teleconference or in person attendance to *OGHpublic meeting@hrsa.gov* by 11:59 p.m. on Tuesday, May 14, 2019. Registration is free. Registrants will receive a registration confirmation once accepted via email.

Requests for Oral Presentations: During registration, you may request to present at the public meeting, and specify which topic(s) you wish to address. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. All requests to make oral presentations are due by the close of registration on Tuesday, May 14, 2019.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify LCDR Charlie Darr (see the **FOR FURTHER INFORMATION CONTACT** section) at least 10 business days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Dated: May 7, 2019.

George Sigounas,

Administrator.

[FR Doc. 2019–09730 Filed 5–10–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Behavior and Social Science of Aging Review Committee, June 05, 2019, 11:00 a.m. to June 06, 2019, 11:00 a.m., Hotel Kabuki, 1625 Post Street, San Francisco, CA 94155 which was published in the **Federal Register** on February 27, 2019, 84 FR 6405.

The meeting notice is amended to change the two-day meetings' starting and ending times on June 5, 2019 to 9:00 a.m.–5:00 p.m. and on June 6, 2019 to 8:30 a.m.–3:00 p.m. The meetings are closed to the public.

Dated: May 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09738 Filed 5–10–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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

The meetings 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 Diabetes and Digestive and Kidney Diseases Initial Review Group; Diabetes, Endocrinology and Metabolic Diseases B Subcommittee.

Date: June 4–6, 2019.

Time: 5:30 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: John F. Connaughton, Ph.D., Chief, Scientific Review Branch, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7007, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7797, *connaughtonj@extra.niddk.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Subcommittee.

Date: June 19–20, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7007, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Digestive Diseases and Nutrition C Subcommittee.

Date: June 19–21, 2019.

Time: 6:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7017, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 7, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–09740 Filed 5–10–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; 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