Treatment.'' The purpose of this draft guidance is to assist sponsors in the development of new drugs for the treatment of uncomplicated urinary tract infections.

This draft guidance defines enrollment criteria for uncomplicated urinary tract infection trials and provides options for clinical trials designed to demonstrate efficacy. An appendix to this draft guidance describes the justification for the noninferiority margin to be used for the option of active-controlled trials designed to demonstrate noninferiority. In addition, this draft guidance reflects recent developments in scientific information that pertain to drugs being developed for the treatment of uncomplicated urinary tract infections.

Issuance of this draft guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs. In 1998, FDA published a draft guidance entitled ''Uncomplicated Urinary Tract Infections—Developing Antimicrobial Drugs for Treatment'' (the 1998 draft guidance). In a **Federal Register** notice dated August 7, 2013 (78 FR 48175), FDA announced an initiative in the Center for Drug Evaluation and Research involving the review of draft guidance documents issued before 2010 to determine their status and to decide whether those guidances should be withdrawn, revised, or finalized with only minor changes. In the same August 7, 2013, **Federal Register** notice, FDA announced that the 1998 draft guidance, as well as other draft guidances, was being withdrawn (78 FR 48175). FDA is now issuing a new draft guidance that revises the recommendations in the 1998 draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on developing drugs for the treatment of uncomplicated urinary tract infections. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

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

Dated: May 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–09929 Filed 5–9–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on June 25, 2018, from 2:00 p.m. to 4:30 p.m. EST. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted one week prior to the meeting at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html.* Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or participate in the public comment session should register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Captain Angela Shen, National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: *nvac@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

The public meeting will include a presentation from the HPV Implementation Working Group on its findings and draft recommendations for strengthening the effectiveness of national, state, and local efforts to improve HPV coverage rates. The presentation will be followed by Committee deliberation and a vote. The public meeting will also include a presentation on the recent HHS report, ''Encouraging Vaccine Innovation: Promoting the Development of Vaccines that Minimize the Burden of Infectious Diseases in the 21st Century,'' which was submitted to Congress in accordance with provisions in the 21st Century Cures Act. All agenda items are tentative and subject to change. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comments at the NVAC meeting during the public comment periods designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit their written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments to the National Vaccine Program Office (*nvac@hhs.gov*) at least five business days prior to the meeting.

Dated: May 7, 2018.

Roula Sweis,

Deputy Director, National Vaccine Program Office.

[FR Doc. 2018–09947 Filed 5–9–18; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Intertek USA, Inc., as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of Intertek USA, Inc., as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Intertek USA, Inc., has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes for the next three years as of June 13, 2017.

DATES: The accreditation and approval of Intertek USA, Inc., as commercial gauger and laboratory became effective on June 13, 2017. The next triennial inspection date will be scheduled for June 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Cassata, Laboratories and Scientific Services, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Intertek USA, Inc., 149 Pintail St., St. Rose, LA 70087, has been approved to gauge and accredited to test petroleum and petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13. Intertek USA, Inc., is approved for the following gauging procedures for petroleum and certain petroleum products set forth by the American Petroleum Institute (API):

API Chapters	Title
3	Tank gauging.
5	Metering.
7	Temperature Determination.
8	Sampling.
11	Volume Correction Factors.
12	Calculations.
17	Maritime Measurements.

Intertek USA, Inc., is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–03	ASTM D–4006	Standard test method for water in crude oil by distillation.
27–04	ASTM D–95	Standard test method for water in petroleum products and bituminous materials by distillation.
27–05	ASTM D–4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	ASTM D–473	Standard test method for sediment in crude oils and fuel oils by the extraction method.
27–08	ASTM D–86	Standard Test Method for Distillation of Petroleum Products.
27–11	ASTM D–445	Standard test method for kinematic viscosity of transparent and opaque liquids (and calculations of dynamic viscosity).
27–13	ASTM D–4294	Standard test method for sulfur in petroleum and petroleum products by energy-dispersive x-ray fluorescence spectrometry.
27–14	ASTM D–2622	Standard Test Method for Sulfur in Petroleum Products (X-Ray Spectrographic Methods).
27–46	ASTM D–5002	Standard Test Method for Density and Relative Density of Crude Oils by Digital Density Analyzer.
27–48	ASTM D–4052	Standard test method for density and relative density of liquids by digital density meter.
27–50	ASTM D–93	Standard Test Methods for Flash-Point by Pensky-Martens Closed Cup Tester.
27–54	ASTM D–1796	Standard test method for water and sediment in fuel oils by the centrifuge method (Laboratory procedure).
27–58	ASTM D–5191	Standard Test Method For Vapor Pressure of Petroleum Products (Mini Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (202) 344–1060. The inquiry may also be sent to *cbp.labhq@dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories: *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Dated: May 2, 2018.

Dave Fluty,

Executive Director, Laboratories and Scientific Services Directorate.

[FR Doc. 2018–10020 Filed 5–9–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of AmSpec LLC (Ferndale, WA) as a Commercial Gauger and Laboratory

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of accreditation and approval of AmSpec LLC (Ferndale, WA) as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that AmSpec LLC (Ferndale, WA) has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 24, 2017.

DATES: AmSpec LLC (Ferndale, WA) was approved and accredited as a commercial gauger and laboratory as of August 24, 2017. The next triennial inspection date will be scheduled for August 2020.

FOR FURTHER INFORMATION CONTACT: Christopher J. Mocella, Laboratories and Scientific Services Directorate, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Suite 1500N, Washington, DC 20229, tel. 202–344–1060.