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 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' Section 503B (21 U.S.C. 353b), added to the FD&C Act by the Drug Quality and Security Act in 2013, describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee-1) (concerning drug supply chain security requirements). One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound drug products using a bulk drug substance unless either: (1) It appears on a list established by the Secretary of Health and Human Services identifying bulk drug substances for which there is a clinical need (see section 503B(a)(2)(A)(i) of the FD&C Act) (503B Bulks List) or (2) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

This guidance addresses FDA policies for developing the 503B Bulks List, including the Agency's interpretation of the phrase ''bulk drug substances for which there is a clinical need,'' as it is used in section 503B of the FD&C Act. The guidance also addresses the factors and processes by which the Agency intends to evaluate and list bulk drug substances.

In the **Federal Register** of March 26, 2018 (83 FR 12952), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period ended on May 25, 2018. FDA received approximately 60 comments on the draft guidance. In response to received comments or on its own initiative, FDA made certain changes to the guidance. For example, FDA has further explained how Congress' limitation on bulk drug substances that can be used in compounding under section 503B helps to preserve the integrity of the new drug approval process and identified the process to request that FDA add or remove a bulk drug substance from the 503B Bulks List after the Agency has made a final determination with respect to that substance in the **Federal Register**.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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. Electronic Access

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

Dated: February 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03807 Filed 3–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Written Comments To Inform Development of a National Youth Sports Strategy

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) solicits written comments from the public on specific topics and questions that will inform the development of the National Youth Sports Strategy.

DATES: Written comments will be accepted through 11:59 p.m. E.T. on April 1, 2019.

ADDRESSES: Written public comments will be accepted via email. Instructions for submitting comments are available on the internet at *https://fitness.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina L. Piercy, Ph.D., R.D., Office of Disease Prevention and Health Promotion (ODPHP), Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite LL–100; Rockville, MD 20852; Telephone: (240) 453–8280. Email: *odphpinfo@hhs.gov*.

SUPPLEMENTARY INFORMATION: Executive Order 13824 directs the development of a National Strategy on Youth Sports and outlines the key pillars that the strategy will address. The Office of Disease Prevention and Health Promotion and the President's Council on Sports, Fitness & Nutrition are leading the development of this strategy.

Key Pillars of Youth Sports Strategy

1. Increase awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition;

2. Promote private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition;

3. Develop metrics that gauge youth sports participation and physical activity to inform efforts that will

improve participation in sports and regular physical activity among young Americans; and

4. Establish a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs.

Written Public Comments: Written comments to inform the development of the strategy are encouraged from the public and will be accepted via email until 11:59 p.m. E.T. April 1, 2019. Instructions for submitting comments are available at *https://fitness.gov*. HHS requests that commenters respond to the questions posed on *https://fitness.gov*. A subsequent public comment period will open this summer to provide comments on the draft strategy report.

Dated: February 19, 2019.

Donald Wright,

Deputy Assistant Secretary for Health Disease Prevention and Health Promotion.

[FR Doc. 2019–03788 Filed 3–1–19; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2019 Schedule

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: 2019 public meeting dates of the Health Information Technology Advisory Committee.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with section 4003(e) of the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the National Coordinator for Health Information Technology (National Coordinator). The HITAC will hold public meetings throughout 2019. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Lauren Richie, Designated Federal Officer, at *Lauren.Richie@hhs.gov,* or (202) 205–7674.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition

The HITAC is comprised of at least 25 members, of which:

- No fewer than 2 members are advocates for patients or consumers of health information technology;
- 3 members are appointed by the HHS Secretary
  - 1 of whom shall be appointed to represent the Department of Health and Human Services and
  - 1 of whom shall be a public health official;
- 2 members are appointed by the majority leader of the Senate;
- 2 members are appointed by the minority leader of the Senate;
- 2 members are appointed by the Speaker of the House of Representatives;
- 2 members are appointed by the minority leader of the House of Representatives; and
- Other members are appointed by the Comptroller General of the United States.

Members will serve for one-, two-, or three-year terms. All members may be reappointed for subsequent three-year terms. Each member is limited to two three-year terms, not to exceed six years of service. After establishment, members shall be appointed for a three-year term. Members serve without pay, but will be provided per-diem and travel costs for committee services.

Recommendations

The HITAC recommendations to the National Coordinator are publicly available at *https://www.healthit.gov/topic/federal-advisory-committees/recommendations-national-coordinator-health-it.*

Public Meetings

The schedule of meetings to be held in 2019 is as follows:

- February 20, 2019 from approximately 9:30 a.m.. to 2:30 p.m./Eastern Time (virtual meeting)
- March 19–20, 2019 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time each day at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- April 10, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time at the Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008
- April 25, 2019 from approximately 9:30 a .m. to 2:30 p.m./Eastern Time (virtual meeting)
- May 13, 2019 from approximately 9:30 a .m. to 2:30 p.m./Eastern Time (virtual meeting)
- June 19, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- September 17, 2019 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time at the Key Bridge Marriott Hotel, 1401 Lee Highway, Arlington, Virginia 22209
- October 16, 2019 from approximately 9:30 a.m. to 2:30 p.m./Eastern Time (virtual meeting)
- November 13, 2019 from approximately 9:30 a.m. to 2:30 p.m./ Eastern Time (virtual meeting)

All meetings are open to the public. Additional meetings may be scheduled as needed. For web conference instructions and the most up-to-date information, please visit the HITAC calendar on the ONC website, *http://www.healthit.gov/FACAS/calendar.*

Contact Person for Meetings: Lauren Richie, *lauren.richie@hhs.gov* . A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Please email Lauren Richie for the most current information about meetings.

Agenda: As outlined in the 21st Century Cures Act, the HITAC will develop and submit recommendations to the National Coordinator on the topics of interoperability, privacy and security, and patient access. In addition, the committee will also address any administrative matters and hear periodic reports from ONC. ONC intends to make background material available to the public no later than 24 hours prior to the meeting start time. If ONC is unable to post the background material on its website prior to the meeting, the material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on ONC's website after the meeting, at *http://www.healthit.gov/hitac.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person prior to the meeting date. An oral public comment period will be scheduled at each meeting. Time allotted for each presentation will be limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled public comment period, ONC will take written comments after the meeting.