

Estimated Time per Response: The time per response is estimated at 2.5 person-hours for reporting requirements.

Total Annual Burden: For the 12 carriers with weekly reporting, the burden is calculated as $12 \times 52 \times 2.5$ hours = 1,560 hours.

William Cody,

Secretary.

[FR Doc. 2023-11082 Filed 5-23-23; 8:45 am]

BILLING CODE 6730-02-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than June 23, 2023.

A. Federal Reserve Bank of San Francisco: (Joseph Cuenco, Assistant Vice President, Formations & Transactions) 101 Market Street, San Francisco, California 94105-1579.

Comments can also be sent electronically to: sf.fisc.comments.applications@sf.frb.org.

1. *VB&T Holding Company, LLC;* to become a bank holding company

through the formation of its subsidiary bank, Zenith Bank & Trust, both of Scottsdale, Arizona.

Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2023-11068 Filed 5-23-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-E-2361; FDA-2020-E-2362; and FDA-2020-E-2363]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENSPRYNG; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is correcting a notice that appeared in the *Federal Register* of July 13, 2022. The document determined the regulatory review period for ENSPRYNG. After review of a timely request for reconsideration by the applicant of the calculation of the applicable regulatory review period of the biologic product ENSPRYNG in that notice, FDA has determined that a revision of the supplementary information section is warranted. This notice corrects the applicable regulatory review period language.

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: In the *Federal Register* of July 13, 2022 (87 FR 41724), on page 41725, in the second column, under "II. Determination of Regulatory Review Period," the first two sentences should be corrected to read as follows: "FDA has determined that the applicable regulatory review period for ENSPRYNG is 2,494 days. Of this time, 2,128 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase."

Dated: May 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-10979 Filed 5-23-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2023 Schedule of Meetings

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

ACTION: Notice of meetings.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with 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 2023. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Michael Berry, Designated Federal Officer, at Michael.Berry@hhs.gov, (202) 701-0795.

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 serve for one-, two-, or three-year terms. All members may be reappointed for a subsequent three-year

term. Each member is limited to two three-year terms, not to exceed six years of service. Members serve without pay, but will be provided per-diem and travel costs for committee services, if warranted.

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 2023 is as follows:

- January 19, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- February 8, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- March 9, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- April 12, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- May 17, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- June 15, 2023, from approximately 9:30 a.m. to 4:00 p.m./Eastern Time at the Mary E. Switzer Federal Building, Suite 1400, 330 C Street SW, Washington, DC 20024 (virtual meeting option available)
- July 13, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- August 17, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- September 14, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- October 19, 2023, from approximately 10:00 a.m. to 3:00 p.m./Eastern Time (virtual meeting)
- November 9, 2023, from approximately 9:30 a.m. to 4:00 p.m./Eastern Time at the Mary E. Switzer Federal Building, Suite 1400, 330 C Street SW, Washington, DC 20024 (virtual meeting option available)

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, www.healthit.gov/topic/federal-advisory-committees/hitac-calendar.

Contact Person for Meetings: Michael Berry, Michael.Berry@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 Michael Berry 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, patient access, and use of technologies that support public health. 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 on ONC's website after the meeting, at 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 commenter 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.

Persons attending in-person HITAC meetings must register in advance; virtual attendance is offered as an alternative. If attending in-person, please allow time to clear building security. All visitors will be escorted to the designated meeting room. Please note that access to electrical outlets may be limited or unavailable.

ONC welcomes the attendance of the public at its HITAC meetings. If you require special accommodations due to a disability, please contact Michael Berry at least seven (7) days in advance of the meeting.

Notice of these meetings are given under the Federal Advisory Committee Act (Pub. L. No. 92-463, 5 U.S.C., app. 2).

Dated: May 12, 2023.

Michael Berry,

Designated Federal Officer, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2023-11062 Filed 5-23-23; 8:45 am]

BILLING CODE 4150-45-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 on Drug Abuse Initial Review Group; Career Development Education and Training Study Section.

Date: June 29, 2023.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sindhu Kizhakke Madathil, Ph.D., Scientific Review Officer, Division of Extramural Research, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827-5702, sindhu.kizhakkemadathil@nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA-K Alternate SEP.

Date: June 30, 2023.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 435-1258, marisa.srivareerat@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)