described in section 505(o)(3)(B) of the FD&C Act.[4]

In April 2011, FDA issued a guidance describing how it would implement section 505(o) of the FD&C Act. At that time, the ARIA system was still in early development. The ARIA system is now officially launched, and FDA must consider the system's sufficiency to meet the purposes of section 505(o)(3)(B) of the FD&C Act to determine if a postmarketing study or clinical trial is necessary. This draft guidance revises the guidance for industry of the same name issued on April 1, 2011 (76 FR 18226). Significant changes from the 2011 version include explaining how FDA considers the reporting under section 505(k)(1) of the FD&C Act and the ARIA system when determining their sufficiency for the purposes under section 505(o)(3)(B) of the FD&C Act. The guidance is also being revised to provide examples of postmarketing requirements under section 505(o)(3) of the FD&C Act to assess a potential reduction in the expected effectiveness of a drug under certain circumstances. FDA's authority to require these types of studies or trials was clarified by a modification to the definition of *adverse drug experience* at section 505–1(b)(1)(E) of the FD&C Act (21 U.S.C. 505–1(b)(1)(E)) enacted under section 3041 of the SUPPORT Act (Pub. L. 115–271).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking on implementation of section 505(o)(3)(B) of the FD&C Act.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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 following collections of information for postmarketing reports and clinical data in 21 CFR 314.50, 314.80, 314.81, 314.98, 314.430, and 314.610(b), subpart I have been approved under OMB control number 0910–0001: (1) Preparing and submitting reports pertaining to safety, postmarketing commitments and preparing and submitting spontaneous and periodic reports, including active postmarket risk identification (using electronic health care data) and any milestones or submissions for which projected dates were specified as part of the postmarketing commitment; (2) submitting a proposed timetable of the postmarketing commitments; (3) preparing registries and submitting them when appropriate; (4) designing meta-analyses to evaluate statistical analyses of data; (5) preparing assay procedures; and (6) prepare a plan or approach for approval an NDA when human efficacy studies are not ethical or feasible.

The following collections of information for postmarketing studies and clinical trials (including various patient populations) in 21 CFR 312.23 have been approved under OMB control number 0910–0014: (1) Conducting in vitro laboratory tests and studies to compare pregnancy incidence an pregnancy outcomes and/or child outcomes for patients exposed to a drug; (2) submitting an introductory statement and general investigational plan, including a drug's pharmacological class; and (3) submitting protocols for drug safety and pharmacology and toxicology information.

The collections of information in 21 CFR 310.305, 314.80, and 314.98 for submitting adverse event information to the FDA Adverse Event Reporting System have been approved under OMB control numbers 0910–0230 and 0910–0291; the collections of information in 21 CFR 312.47 and 312.82 for submitting a meeting request to appeal the conduct of a postmarketing study or clinical trial have been approved under OMB control number 0910–0430 (and guidance for industry and review staff entitled ''Formal Dispute Resolutions: Appeals Above the Division Level'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm343101.pdf*).

The following collection of information in § 314.510 has been approved under OMB control number 0910–0765: Requests for serious or life-threatening diseases or conditions that may be granted accelerated approval if FDA determines the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality or other clinical benefit.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23312 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

[4] Section 505(o)(3)(D)(ii) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Evidence-based Screening in Diverse Adult Populations.

Date: November 15, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Karen Nieves Lugo, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health Bethesda, MD 20892, 301–594–9088, *karen.nieveslugo@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: November 18–19, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186,

MSC 7804, Bethesda, MD 20892, (301) 437–8135, *huzhuang@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Microbiology Research Enhancement Review.

Date: November 18, 2019.

Time: 8:00 a.m. to 6:00 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: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301–996–5819, *zhengli@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery and Development.

Date: November 18, 2019.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AI19–024/025: US South Africa Program for Collaborative Biomedical Research.

Date: November 18, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–435–1149, *marci.scidmore@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Electronic Nicotine Delivery Systems (ENDS): Population, Clinical and Applied Prevention Research.

Date: November 18, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Miriam Mintzer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, Bethesda, MD 20892, 301–523–0646, *mintzermz@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.

Date: November 19, 2019.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Biology.

Date: November 19, 2019.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–451–4467, *morrowcs@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Retinopathies, Cornea Regeneration and Strabismus.

Date: November 19, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205, MSC7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Services Organization and Delivery.

Date: November 19, 2019.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Administrator, Center for Scientific of Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, 301–827–4446, *bellingerjd@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23278 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute, November 4, 2019, 9:00 a.m. to 3:45 p.m., National Institutes of Health, Building 45, Natcher Building, Conference Room D, 45 Center Drive, Bethesda, MD 20892, which was published in the **Federal Register** on February 15, 2019, 84 FR 4487.

This meeting notice is amended to add an open session from 9:05 a.m. to 9:35 a.m. to present Remarks from the Acting Director, NCI and to change the meeting end time from 3:45 p.m. to 5:00 p.m. The meeting is partially closed to the public.

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23282 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel; Identification of Genetic and Genomic Variants by Next-Gen Sequencing in Non-human Animal Models (U01).

Date: November 1, 2019.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001