

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 this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:**

Lauren Belcher or Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: [AskCTPRegulations@fda.hhs.gov](mailto:AskCTPRegulations@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Submission of Plans for Cigarette Packages and Cigarette Advertisements.” The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) to direct FDA to issue regulations requiring each cigarette package and advertisement to bear a new textual warning label statement accompanied by color graphics depicting the negative health consequences of smoking (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). The Tobacco Control Act also modified the requirements of the FCLAA regarding the submission of cigarette plans for the random and equal display and distribution of required warnings on cigarette packages and quarterly rotation of required warnings in cigarette advertisements. It also requires that such cigarette plans be submitted to

FDA for review and approval, rather than to the Federal Trade Commission.

FDA issued a rule entitled “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements” on March 18, 2020. The rule specifies the color graphics that must accompany the new textual warning label statements and establishes marketing requirements for cigarette packages and advertisements. The marketing requirements include, among other things, submission of a cigarette plan that provides for the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements, as described under section 4 of FCLAA.

This guidance provides recommendations related to preparing and submitting those cigarette plans. It discusses the regulatory requirements to submit cigarette plans as well as:

- Who submits a cigarette plan;
- the scope of a cigarette plan;
- when to submit a cigarette plan;
- what information should be submitted as part of a cigarette plan;
- where to submit a cigarette plan;

and

- what approval of a cigarette plan means.

FDA previously published a draft version of the guidance and sought public comment (84 FR 71957, December 30, 2019) (announcing the availability of the draft guidance). Among other things, comments express some concerns, such as about printing processes, as well as the difficulty of achieving random and equal display and distribution of required warnings. FDA has considered the comments it received, and included revisions in the final guidance that: (1) Discuss, per the final rule, that manufacturers may print different required warnings on front and rear panels of a cigarette package; (2) recognize that some level of deviation is appropriate given the language of the FCLAA; and (3) provide updated examples in an appendix to the guidance that demonstrate how random and equal display and distribution may be achieved with various printing methods, including those used by small manufacturers.

**II. Significance of Guidance**

FDA is issuing this guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA regarding the submission of cigarette plans for cigarette packages and advertisements. 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.

**III. Paperwork Reduction Act of 1995**

This guidance refers to collections of information described in FDA’s rule on “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements,” which this guidance is intended to interpret. 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. 3501-3521). The information collection provisions in the final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

**IV. Electronic Access**

Persons with access to the internet may obtain an electronic version of the guidance at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm>.

Dated: March 17, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-05936 Filed 3-19-20; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Meeting of the Advisory Council on Blood Stem Cell Transplantation**

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

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary’s Advisory Council on Blood Stem Cell Transplantation (ACBSCT) has scheduled a public meeting. Information about ACBSCT and the agenda for this meeting can be found on the ACBSCT website at <https://bloodstemcell.hrsa.gov/about/advisory-council>

**DATES:** April 27, 2020, 8:00 a.m.–4:00 p.m. Eastern Time (ET).

**ADDRESSES:** This meeting will be held by webinar and conference call. The webinar link, conference call-in number, registration information, and meeting materials can be accessed

through the registration link on the ACBSCT website at <https://bloodstemcell.hrsa.gov/about/advisory-council>.

**FOR FURTHER INFORMATION CONTACT:**

Robert Walsh, Designated Federal Official, (DFO), at Division of Transplantation, HRSA, 5600 Fishers Lane, 8W60, Rockville, Maryland 20857; 301-443-6839; or [RWalsh@hrsa.gov](mailto:RWalsh@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** ACBSCT provides advice and recommendations to the Secretary of HHS (Secretary) and the HRSA Administrator on the activities of the C.W. Bill Young Cell Transplantation Program (CWBYCTP) and the National Cord Blood Inventory (NCBI) Program. The principal purpose of these programs is to make blood stem cells from adult donors and cord blood units available for patients who need a transplant to treat life-threatening conditions such as leukemia, and who lack a suitably matched relative who can be the donor.

During the April 27, 2020, meeting, the ACBSCT will discuss issues related to increasing access to transplantation (including the utilization of cord blood and other types of cellular therapy). Agenda items are subject to change as priorities dictate. Refer to the ACBSCT website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT should be sent to Robert Walsh, DFO, using the contact information above at least 3 business days prior to the meeting.

Individuals planning to participate who need special assistance or another reasonable accommodation should notify Robert Walsh at the address and phone number listed above at least 10 business days prior to the meeting.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2020-05921 Filed 3-19-20; 8:45 am]

**BILLING CODE 4165-15-P**

**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; Myalgic Encephalomyelitis/Chronic Fatigue Syndrome.

*Date:* April 14, 2020.

*Time:* 11:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* M. Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, (301) 435-1766, [bennetc3@csr.nih.gov](mailto:bennetc3@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Special Topics in Human Aging.

*Date:* April 14, 2020.

*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 Dr., Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, [edwardss@csr.nih.gov](mailto:edwardss@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR 18-731 Cancer Workforce Diversity.

*Date:* April 16, 2020.

*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 Dr., Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Reigh-Yi Lin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827-6009, [lin.reigh-yi@nih.gov](mailto:lin.reigh-yi@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: March 16, 2020.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-05816 Filed 3-19-20; 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; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, March 30, 2020, 05:00 p.m. to March 31, 2020, 05:00 p.m., The Bethesda Hotel, Tapestry Collection by Hilton, 8120 Wisconsin Ave, Bethesda, MD, 20814 which was published in the **Federal Register** on February 11, 2020, 85 FR 7772.

The meeting notice is amended to change the Meeting Format from Regular Meeting on March 30-31, 2020 to a Teleconference Meeting on March 30-31, 2020. The meeting is closed to the public.

Dated: March 16, 2020.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-05822 Filed 3-19-20; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shriver National Institute of Child Health & Human Development Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the National Institute of Child Health and Human Development Special Emphasis Panel, Fertility and Infertility Preservation for Patients with Diseases that Previously Precluded Reproduction, April 15, 2020, 08:00 a.m. to April 15, 2020, 05:00 p.m., NICHD Offices, 6710B Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on March 06, 2020, 85 FR 10707.