

Products Guidance for Industry and FDA Staff” to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, Room 5129, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Burns or John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled “Postmarketing Safety Reporting for Combination Products Guidance for Industry and FDA Staff.” The guidance provides general information on combination products; how FDA regulates combination products; a summary of the combination product PMSR final rule (21 CFR part 4, subpart B); an overview of which entities are subject to the final rule and what safety reporting requirements apply to such entities; detailed discussion of specific combination product PMSR report types; guidance on where, how, and when to submit PMSR reports to FDA; and hypothetical scenarios that illustrate how to comply with certain combination product PMSR requirements.

FDA carefully considered the comments received on the draft guidance, and revised the guidance as appropriate in response to the comments. Combination PMSR information, including examples to illustrate how to report combination production information in electronic reporting systems, is also available on FDA’s website at <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>. FDA encourages combination product applicants to contact the lead Center for their combination product and/or the Office of Combination Products if they have questions on PMSR compliance.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Postmarketing Safety Reporting for Combination

Products. 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.

III. Electronic Access

Persons with access to the internet may obtain the guidance document at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/combination-products-guidance-documents>.

IV. Paperwork Reduction Act of 1995

This 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 collections of information in 21 CFR 314.80(c) and (e), as well as for 21 CFR 314.81(b) are approved under OMB control numbers 0910-0001, 0910-0230, and 0910-0291. The information collection provisions for 21 CFR 600.80 and 600.81 are approved under OMB control number 0910-0308. Those for 21 CFR 606.170 are approved under OMB control number 0910-0116. Those for 21 CFR 606.171 are approved under OMB control number 0910-0458. The information collection provisions for 21 CFR 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910-0291 and 0910-0437. The information collection provisions for 21 CFR 806.10 and 806.20 are approved under OMB control number 0910-0359. The information collection provisions for 21 CFR 4.102, 4.103, and 4.105 are approved under OMB control number 0910-0834.

Dated: July 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-15595 Filed 7-22-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, with

attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: September 5, 2019.

Closed: 9:00 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Open: 10:30 a.m. to 4:30 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Susan R.B. Weiss, Ph.D. Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, NSC, Room 5274, MSC 9591, Rockville, MD 20892, 301-443-6487, sweiss@nida.nih.gov.

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute’s/Center’s home page: www.drugabuse.gov/NACDA/NACDAHome.html, where an agenda and

any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 17, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

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(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: July 16, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

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BILLING CODE 4140-01-P

proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Ellen Gadbois, Office of the Director, NIH, Building 1, Room 218, MSC 0166, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496-9838 or email your request, including your address to: gadboisel@od.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 16, 2019, page 22153 (84 FR 22153) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH Office of the Director may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Request for Human Embryonic Stem Cell Line to be approved for Use in NIH Funded Research. OMB No. 0925-0601—Extension—Expiration Date 07/31/2019—Office of the Director, National Institutes of Health (NIH).

Need and Use of Information Collection: The form is used by applicants to request that human embryonic stem cell lines be approved for use in NIH funded research. Applicants may submit applications at any time.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 255 per respondent.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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; Impaired Wound Healing in Aging.

Date: August 9, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Inese Z Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301-435-1034, beitinsi@csr.nih.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request: Request for Human Embryonic Stem Cell Line To Be Approved for Use in NIH Funded Research (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
NIH grantees and others with hESC lines	5	3	17	255
Total	15	255