

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA-2017-D-6580]
Drug Products Labeled as Homeopathic; Draft Guidance for Staff and Industry; Availability; Extension of Comment Period
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice entitled “Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry; Availability” that appeared in the **Federal Register** of December 20, 2017. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published December 20, 2017 (82 FR 60403). Submit either electronic or written comments on the draft guidance by May 21, 2018, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-D-6580 for “Drug Products Labeled as Homeopathic; Draft Guidance for Staff and Industry; Availability; Extension of Comment Period.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked 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 draft 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993-0002, 301-796-3600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:
I. Background

In the **Federal Register** of December 20, 2017 (82 FR 60403), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and staff entitled “Drug Products Labeled as Homeopathic.” FDA is extending the comment period until May 21, 2018. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying publication of the final version of the guidance.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/>

Guidances/default.htm, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: March 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-05659 Filed 3-20-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of The Director, National Institutes of Health; 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 Advisory Committee to the Director, National Institutes of Health.

The meeting will be held as a teleconference call only and is open to the public to dial-in for participation. Individuals who plan to dial-in to the meeting and need special assistance or other reasonable accommodations in order to do so, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: April 6, 2018.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: Report from the Working Group on Ethical Consideration for Industry Partnership on Research to Help End the Opioid Crisis.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Telephone Conference Call), 888-324-9616, Access Code: 1986191.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301-496-4272, Woodgs@od.nih.gov.

Any interested person may file written comments with the committee by forwarding the 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: <http://acd.od.nih.gov>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired

Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: March 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-05740 Filed 3-20-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Approaches to Identify and Care for Individuals with Inherited Cancer Syndromes.

Date: April 26, 2018.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W640 Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Bethesda, MD 20892-9750, 240-276-5179, saejeong.kim@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP-3; NCI Clinical and Translational Exploratory/Developmental Studies.

Date: June 5-6, 2018.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities,

National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Bethesda, MD 20892-9750, 240-276-7286, salvucco@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 16, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-05737 Filed 3-20-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Center for Advancing Translational Sciences.

The meetings 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 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: Cures Acceleration Network Review Board.

Date: May 10, 2018.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: Report from the Institute Director.
Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 1072, Bethesda, MD