

FDA in writing. FDA is also requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for an upcoming vacancy effective with this notice.

**DATES:** Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by July 31, 2019 (see sections I and III of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by July 31, 2019.

**ADDRESSES:** All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nominations should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing FDA's Advisory Committee Membership Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002. Information about becoming a member of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:** Margaret Ames, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5264, Silver Spring, MD 20993-0002, 301-796-5960, Fax: 301-847-8505, email: [Margaret.Ames@fda.hhs.gov](mailto:Margaret.Ames@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 520 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360j), as amended, provides that DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for a nonvoting industry representative to fill an upcoming vacancy on DGMPAC. FDA is publishing a separate document announcing the request for notification for voting members on DGMPAC.

### I. Function of DGMPAC

DGMPAC reviews proposed regulations regarding good manufacturing practices governing the methods used in, and the facilities and controls used for, the manufacture, packaging, storage, installation, and servicing of devices, and makes recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidance developed to assist the medical device industry in meeting the good manufacturing practice requirements and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

### II. Qualifications

Persons nominated for DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work as described in the committee's function.

### III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations, and a list of all nominees along with their current résumé. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

### IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory

Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.)

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the device manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-2016]

#### **Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations." The purpose of this guidance is to assist sponsors with the development of drugs for treatment or prevention of the serious cutaneous manifestations of the heterogeneous group of disorders collectively known as epidermolysis bullosa (EB). This guidance focuses on drug development

and trial design issues specific to the treatment of EB, including FDA's current thinking on clinical trial endpoint considerations. There is not yet sufficient clinical trial experience to establish definitive endpoints. This guidance incorporates the comments received for and finalizes the draft guidance of the same name issued on June 18, 2018.

**DATES:** The announcement of the guidance is published in the **Federal Register** on July 1, 2019.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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-2018-D-2016 for "Epidermolysis

Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations." 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 this 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 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 guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Barbara Gould, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5166, Silver Spring, MD 20993-0002, 301-796-4224; 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**

*FDA is announcing the availability of a guidance for industry entitled "Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations." The purpose of this guidance is to assist sponsors with the development of drugs for treatment or prevention of the serious cutaneous manifestations of the heterogeneous group of disorders collectively known as EB. This guidance focuses on drug development and trial design issues specific to the treatment of EB, including FDA's current thinking on endpoint considerations. There is not yet sufficient clinical trial experience to establish definitive endpoints. This guidance incorporates the comments received for and finalizes the draft guidance of the same name issued on June 18, 2018 (83 FR 28240). All the public comments received on the draft guidance have been considered, and the guidance has been revised as appropriate along with a few editorial changes.*

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 "Epidermolysis Bullosa: Developing Drugs for Treatment of Cutaneous Manifestations." 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.

##### **II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information that

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 part 312 have been approved under OMB control number 0910–0014.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <https://www.regulations.gov>.

Dated: June 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–13969 Filed 6–28–19; 8:45 am]

**BILLING CODE 4164–01–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; Member Conflict: HIV/AIDS Population and Behavioral Research.

*Date:* July 16, 2019.

*Time:* 11:00 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:* John H. Newman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, (301) 435–0628, [newmanjh@csr.nih.gov](mailto:newmanjh@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Population Sciences and Epidemiology.

*Date:* July 24, 2019.

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

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–2309, [fothergillke@mail.nih.gov](mailto:fothergillke@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Glial development, myelination and remyelination.

*Date:* July 24, 2019.

*Time:* 1:00 p.m. to 4:00 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:* Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435–1239, [guthriep@csr.nih.gov](mailto:guthriep@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: June 25, 2019.

**Sylvia L. Neal,**

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

[FR Doc. 2019–13941 Filed 6–28–19; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HOMELAND SECURITY

**[DHS–2019–0029]**

### Project 25 Compliance Assessment Program (P25 CAP)

**AGENCY:** Science and Technology Directorate, Department of Homeland Security.

**ACTION:** Notice of information collection; request for comment.

**SUMMARY:** The Department of Homeland Security (DHS) invites the general public to comment on updated data collection forms for DHS Science and Technology (S&T) Directorate's Project 25 (P25) Compliance Assessment Program (CAP): Supplier's Declaration of Compliance (SDoC) (DHS Form 10044 (6/08)) and an accompanying Summary Test Report (STR) (DHS Form 10056 (9/08)). The collections are posted on the

dhs.gov website (<https://www.dhs.gov/science-and-technology/p25-cap>). The attacks of September 11, 2001, and the destruction of Hurricane Katrina made apparent the need for emergency response radio systems that can interoperate, regardless of which organization manufactured the equipment. Per congressional direction, DHS and the National Institute of Standards and Technology (NIST) developed the P25 CAP to improve the emergency response community's confidence in purchasing land mobile radio (LMR) equipment built to P25 LMR standards. Equipment suppliers provide the information to publicly attest to their products' compliance with a specific set of P25 standards. The SDoC, and its STR, which substantiates the declaration, constitutes a company's formal, public attestation of compliance with the standards for the equipment. In turn, first responders at local, tribal, state, and federal levels across multiple disciplines including law enforcement, fire, and emergency medical services personnel, will use this information to identify P25 compliant communications system products. The P25 CAP Program Manager performs a simple administrative review to ensure the documentation is complete and accurate in accordance with the current P25 CAP processes.

**DATES:** Comments are encouraged and accepted until July 31, 2019.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer, via electronic mail to [dhsdeskofficer@omb.eop.gov](mailto:dhsdeskofficer@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:** DHS/S&T System Owner: Sridhar Kowdley, [Sridhar.kowdley@HQ.DHS.GOV](mailto:Sridhar.kowdley@HQ.DHS.GOV), (202) 254–8804 (Not a toll free number).

**SUPPLEMENTARY INFORMATION:** DHS, in accordance with the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collection of information. DHS is soliciting comments on the proposed Information Collection Request (ICR) that is described below. The Department of Homeland Security is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how