

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

*Authority:* 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each state agency requesting federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act].

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023-24185 Filed 11-1-23; 8:45 am]

BILLING CODE 4184-45-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-2809]

#### Advisory Committee; Patient Engagement Advisory Committee; Renewal

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

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Patient Engagement Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Patient Engagement Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 6, 2025, expiration date.

**DATES:** Authority for the Patient Engagement Advisory Committee would have expired on October 6, 2025, unless the Commissioner had formally determined that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Letise Williams, Office of the Center

Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993-0002, 301-796-8398, [Letise.Williams@fda.hhs.gov](mailto:Letise.Williams@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Patient Engagement Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Patient Engagement Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective devices for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee provides advice to the Commissioner of Food and Drugs or designee on complex scientific, issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life measures or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

Pursuant to its Charter, the Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient experience, and healthcare needs of patient groups in the United States, or who are experienced in the work of patient and health professional organizations, methodologies for patient reported outcomes and eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects, as well as other relevant areas. Members will be invited

to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as either as Special Government Employees or non-voting representatives. Federal members will serve as Regular Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

The Commissioner or designee shall also have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members); or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees,

please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: October 30, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–D–4595]

#### **Enforcement Policy for Certain Supplements for Approved Premarket Approval or Humanitarian Device Exemption Submissions; Guidance for Industry and Food and Drug Administration Staff; 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 the final guidance entitled “Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions.” This guidance outlines FDA’s policies and regulatory review expectations after the COVID–19 public health emergency (PHE) for certain limited modifications affecting the safety and effectiveness of a device required to have an approved PMA or the safety and probable benefit of a device required to have an approved HDE. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency’s good guidance practices.

**DATES:** The announcement of the guidance is published in the **Federal Register** on November 2, 2023.

**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–2023–D–4595 for “Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions.” 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, 240–402–7500.

- **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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the

**SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Enforcement Policy for Certain Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 request.

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

Jhumur Banik, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2448, Silver Spring, MD 20993–0002, 240–402–5239 or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

#### **SUPPLEMENTARY INFORMATION:**