4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0008]

General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice—Establishment of Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of the meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee). This meeting was previously announced in the *Federal Register* of September 3, 2025. The amendment is being made to reflect changes in the DATES, ADDRESSES and SUPPLEMENTARY INFORMATION portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 66, Rm. 2404 Silver Spring, MD 20993-0002, Evella.Washington@fda.hhs.gov, 240-447-9160.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 3, 2025 (90 FR 42588), FDA announced that a meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee would be held on October 8, 2025. On page 42588, in the third column, "The meeting will be held virtually on October 8, 2025, from 9 a.m. to 3:30 p.m. Eastern Time", the DATE portion of the document is changed to read as follows:

The meeting will be held virtually on December 10, 2025, from 9 a.m. to 3:30 p.m. Eastern Time.

On page 42588, in the third column to page 42589, in the first column “FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2025-N-0008. The docket will close on November 10, 2025. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 10, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before September 24, 2025, will be provided to the Committee. Comments received after this date will be taken into consideration by FDA. The ADDRESSES portion of the document is changed to read as follows:

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2025-N-0008. The docket will close on January 9, 2026. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 9, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before December 1, 2025, will be provided to the Committee. Comments received after this date will be taken into consideration by FDA.

On page 42589, in the third column, Agenda: On October 8, 2025, the SUPPLEMENTARY INFORMATION portion of the document is changed to read as follows:

Agenda: On December 10, 2025.

On page 42589, in the third column to page 42590, in the first column, “Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions made to the Docket (see ADDRESSES) on or before September 24, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Eastern Time. Those

individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 18, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 22, 2025. The SUPPLEMENTARY INFORMATION portion of the document is changed to read as follows:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions made to the Docket (see ADDRESSES) on or before December 1, 2025, will be provided to the Committee. Oral presentations from the public will be scheduled on December 10, 2025, between approximately 11:30 a.m. and 12:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 3, 2025. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 3, 2025.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 et seq.) and 21 CFR part 14, relating to the advisory committees.

Lowell M. Zeta,

Deputy Commissioner of Strategic Initiatives,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

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