how to respond to it, for a total of 1,843 hours. We assume that fifty percent of the companies invited to participate, or 9,215 companies, will decide to participate, navigate to our web page, and click on the link to the assessment to access it. Once the company accesses the assessment, it will be presented with a two-part screening question. We estimate that all companies will answer the screening question and that it will take 0.1 hour (6 minutes) to read and answer the screening question, for a total of 921.5 hours, rounded to 922 hours. We estimate that only ten percent of those companies, or 921.5 respondents, rounded to 922 respondents, will complete the entire questionnaire. We estimate that it will take, based on the various levels of availability and resources by company, approximately 2 hours on average to compile the necessary information and to respond to all of the questions in the assessment questionnaire, for a total of 1,844 hours.

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

DSCSA small dispenser assessment	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records related to assessment questions response	922	1	922	0.5	461

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We expect that companies will compile information needed to respond to the questions in the assessment questionnaire and that they will keep copies of that information in their records either electronically or on paper. We recommend that companies retain these records for at least a year after the assessment is completed. We estimate that these recordkeeping activities will take approximately 0.5 hour per company, for a total of 461 hours.

TABLE 3—ESTIMATED ONE-TIME THIRD-PARTY DISCLOSURE BURDEN [1]

DSCSA small dispensers assessment	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Coordination with third-party entities related to screener questions	692	2	1,384	0.1	138
Coordination with third-party entities related to assessment questions response	461	2	922	2	1,844
Total	.....	.....	2,306	.....	1,982

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded to the nearest whole number.

We have taken into consideration the time that respondents will spend coordinating with third-party entities (*e.g.,* solution providers, wholesale distributors, consultants). For the screener questions, we assume seventy-five percent of the 922 respondents, or 691.5 respondents, rounded to 692, will work with their respective partnering entities and the average number of partnering entities will be 2, for a total of 1,384 disclosures. We estimate that each disclosure will take approximately 0.1 hours (6 minutes) for a total of 138.4 hours, rounded to 138 hours. For the assessment questionnaire response, we assume fifty percent of the 922 respondents, or 461 respondents, will coordinate with a total of two partners for a total of 922 disclosures. We estimate it will take 2 hours to coordinate with each partner, resulting in a total of 1,844 hours.

Lowell M. Zeta,

Deputy Commissioner of Strategic Initiatives, Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–20643 Filed 11–20–25; 8:45 am]

BILLING CODE 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 **DATES** 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.

[FR Doc. 2025–20608 Filed 11–20–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by January 20, 2026 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*.