II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects and investigational review boards have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 201.56 and 201.57 for the Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications and bioavailability/BE (BA/BE) studies or pharmacogenomic data and the collections of information in part 320 for drug safety reporting have been approved under OMB control numbers 0910–0014 and 0910–0291. The collections of information under 21 CFR part 312.145 pertaining to good clinical practice have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications, ANDAs, and supplemental applications and applicable BA/BE requirements have been approved under OMB control number 0910–0001. The collections of information under the administrative practices and procedures for petitions, hearings, and other administrative proceedings and activities conducted by the FDA under *21 CFR part 10 and 12* are approved under OMB control number 0910–0191. The collections of information for the submission of controlled correspondence, and for meetings pertaining to ANDA approval are approved under OMB control number 0910–0727. The collections of information pertaining to Good Laboratory Practice Regulations have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10703 Filed 5–28–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–5057]

Patient-Focused Drug Development for Nonhealing Chronic Wounds; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Patient-Focused Drug Development for Nonhealing Chronic Wounds.'' The purpose of the public meeting is to obtain patient perspectives about the impact of nonhealing chronic wounds on daily life, patient views on treatment approaches, factors to consider when selecting a treatment, and what they consider when determining whether to participate in a clinical trial.

DATES: The hybrid public meeting will be held on August 25, 2026, from 10:00 a.m. to 4:30 p.m., Eastern Time and will take place in person and virtually. Either electronic or written comments on this public meeting must be submitted by October 26, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The hybrid public meeting will be held in person at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room, Silver Spring, MD 20993–0002, and virtually via a live webcast. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit comments as follows. 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 October 26, 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.

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–2026–N–5057 for ''Patient-Focused Drug Development for Nonhealing Chronic Wounds; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Ethan Gabbour, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–8112, *Ethan.Gabbour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This meeting will provide FDA and other key stakeholders, including medical product developers, health care providers, and federal partners, the opportunity to hear directly from patients, patient representatives, and care partners about their experiences with nonhealing chronic wounds, including how the wounds and associated wound care affect their daily lives, what matters most to them, their current approaches to managing or treating their nonhealing chronic wounds, and what they consider when determining whether to participate in a clinical trial. Chronic wounds are defined as wounds that have failed to proceed through an orderly and timely series of events to produce a functional, durable, and cosmetic closure. When standard of care has been applied to a wound with failure to progress towards healing within 4 weeks, that wound is generally considered chronic. These wounds most commonly occur on the feet and lower legs. They are more prevalent in individuals with underlying conditions such as diabetes, malnutrition, connective tissue diseases, poor circulation, or compromised immune systems. They can cause lasting pain, sleep difficulties, limited movement, and depression. Existing management of wounds primarily consists of wound dressings and medical devices that target the body's natural healing process. However, the exact management or treatment protocol is based on the type of wound and its underlying cause.

For each topic, a brief discussion by a patient panel will begin the dialogue. This discussion will be followed by a facilitated discussion inviting comments from patients, patient representatives, and care partners.

In addition to input generated through this public meeting, FDA is interested in receiving patient and patient representative input through written comments, which can be submitted to the public docket (see **ADDRESSES**). When submitting comments, if you are commenting on behalf of a patient, please indicate that you are doing so, and answer the questions as much as possible from the patient perspective.

FDA will post the agenda and other meeting materials approximately 5 days before the meeting at: *https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-fda-led-patient-focused-drug-development-meeting-nonhealing-chronic-wounds.*

II. Topics for Discussion at the Public Meeting

On August 25, 2026, FDA will conduct a public meeting entitled ''Patient-Focused Drug Development for Nonhealing Chronic Wounds.'' FDA is interested in obtaining patient and care partner perspectives on the impact of nonhealing chronic wounds on daily life, on approaches to treat such wounds, and on considerations for clinical trial participation.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-fda-led-patient-focused-drug-development-meeting-nonhealing-chronic-wounds.* Please indicate either in-person or virtual attendance, and provide complete contact information for each attendee, including name, affiliation, and email.

Registration is free for both in-person and virtual attendance. In-person attendance is based on space availability, with priority given to early registrants. Persons interested in attending this public meeting in person must register by August 23, 2026, 11:59 p.m., Eastern Time. Virtual attendees can register and join at any time through the conclusion of the meeting. Early registration for in-person attendance is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 10:00 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact *Ethan.Gabbour@fda.hhs.gov* no later than August 18, 2026. Please note that closed captioning will be available for online attendees.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting *https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-fda-led-patient-focused-drug-development-meeting-nonhealing-chronic-wounds.* This webcast can also be accessed via: *https://www.zoomgov.com/j/1657415115?pwd=9aZFuJFfpDVCQ99WWLjoByKzYDwBRS.1.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/fda-public-meeting-fda-led-patient-focused-drug-development-meeting-nonhealing-chronic-wounds.*

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–10752 Filed 5–28–26; 8:45 am]

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