U.S. FOOD & DRUG ADMINISTRATION

Hybrid Public Meeting on Patient-Focused Drug Development for Nonhealing Chronic Wounds

US Food and Drug Administration

Tuesday, August 25, 2026

IN-PERSON LOCATION

FDA White Oak Campus
10903 New Hampshire Avenue
Building 31, Room 1503
Silver Spring, MD 20993
United States

LIVE WEBCAST:

https://fda.mediasite.com/mediasite/Play/56a0735c3c3842e294851d6d507434981d

AGENDA

10:00 – 10:05 am	**Welcome** Robyn Bent, R.N., M.S. *Director of Patient-Focused Drug Development, Office of the Center Director (OCD), Center for Drug Evaluation and Research (CDER), FDA*
10:05 – 10:10 am	**Opening Remarks** Michelle Tarver, M.D., Ph.D *Director of the Center for Devices and Radiological Health (CDRH), FDA*
10:10 – 10:20 am	**Overview of FDA's Patient Focused Drug Development Program** Ethan Gabbour, M.S. *Public Health Analyst, Patient-Focused Drug Development, OCD, CDER, FDA*
10:20 – 10:30 am	**Clinical Overview and Background on Nonhealing Chronic Wounds** Vickie R Driver, D.P.M, M.S. *President and Board Chair, Wound Care Collaborative Community (WCCC), Professor, Washington State University, School of Medicine*
10:30 – 10:40 am	**Overview of the Discussion Format** Robyn Bent, R.N., M.S. *Director of Patient-Focused Drug Development, OCD, CDER, FDA*
10:40 – 11:10 am	**Topic 1: Health Effects and Daily Impacts** A panel of patients and/or care partners will provide comments to start the discussion on significant health effects and daily impacts of nonhealing chronic wounds.
11:10 am – 12:15 pm	**Large Group Facilitated Discussion on Session 1** Patients and care partners in the audience are invited to add to the dialogue.

12:15 pm – 1:15 pm	**Lunch Break**
1:15 pm – 1:45 pm	**Topic 2: Current Approaches to Treatment** A panel of patients and/or care partners will provide comments to start the discussion on current approaches to treating nonhealing chronic wounds.
1:45 pm – 2:50 pm	**Large Group Facilitated Discussion on Session 2** Patients and/or care partners in the audience are invited to add to the dialogue.
2:50 pm – 3:00 pm	**Break**
3:00 pm – 3:30 pm	**Topic 3: Patient Perspectives on Clinical Trials** A panel of patients and/or care partners will provide comments to start the discussion on clinical trials related to nonhealing chronic wounds.
3:30 pm – 4:25 pm	**Large Group Facilitated Discussion on Session 3** Patients and/or care partners in the audience are invited to add to the dialogue.
4:25 pm – 4:30 pm	**Closing Remarks** Maryjoy Mejia, M.D. *Medical Officer, Division of Dermatology and Dentistry, Office of New Drugs, CDER*

DISCUSSION QUESTIONS

Topic 1: Health Effects and Daily Impacts

1. What types of chronic wound/s do you have, and how long have you been living with it?
    a. Has your wound ever improved for a time without fully closing? Please describe what that was like.
2. What are the top 1-3 ways your chronic wound affects your daily life the most? *(Examples may include pain, difficulty walking, avoiding social activities, unpleasant odor, etc.).*
    a. If you have more than one wound, do they affect your daily life differently? How?
3. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your wound? *(Examples of activities may include walking, exercising, working, participating in social activities, personal hygiene, intimacy with a spouse or partner, etc.).*
4. When you think about your wound, what is a "good day" like for you? What is a "bad day" like?
5. In relation to your wound, how has your overall condition changed over time?
    a. Do you feel your condition is well-managed today?
6. What concerns you most about living with your wound?

Topic 2: Current Approaches to Treatment

1. What are you currently doing to help manage or treat your wound, if anything? *(Examples: wound dressings, prescription medications, removal of dead tissue, casts or cushions, diet and exercise).*
    a. In your own words, what does "healing" mean to you? What would healing look or feel like?
2. How well have your current treatments helped address the effects of chronic wounds that are most troubling to you?

3. What are the biggest challenges or downsides you have experienced with your treatments? *(Examples may include bothersome side effects, pain during procedures, lack of effectiveness, etc.).*
4. Even if a treatment does not cure your wound completely, what improvements would be meaningful to you?
    a. Are there risks, side effects, or treatment burdens that you would be willing to accept if it meant your wound could heal faster or stay healed longer?
    b. What does "effective treatment" mean to you? Examples may include full closure, less drainage, less pain, fewer dressing changes, easier walking, and better sleep. Would a treatment still be helpful to you if it did not fully close the wound but improved your daily life?

Topic 3: Patient Perspectives on Clinical Trials

1. If you considered participating or have participated in a clinical study for chronic wounds, please tell us about your experience. Was there anything about the clinical trial that made it easier for you to participate or consider participating?
    a. Was there anything about the clinical trial that made it more difficult for you to participate?
2. If you were deciding whether to join a clinical trial, how important would the following be to you?
    a. The treatment being studied. *(Examples may include possible side effects and how the treatment is given- such as pills, injections, or devices).*
    b. The trial logistics. *(Examples may include how long the study lasts, whether visits are in-person or remote, and how far you must travel).*
3. What results or improvements are most important for a clinical trial to measure? Examples may include reduced pain, fewer dressing changes, faster healing, and improved mobility.

SUBMIT A COMMENT TO THE PUBLIC DOCKET

We encourage participants to submit written comments to the public docket by October 26, 2026: https://www.regulations.gov/document/FDA-2026-N-5057-0001 or visit www.regulations.gov and search for FDA-2026-N-5057.