

Center for Drug Evaluation and Research (CDER)
Virtual Public Meeting on Patient-Focused Drug Development for Vitiligo

US Food and Drug Administration

Monday, March 8, 2021

LIVE WEBCAST: <https://fda.yorkcast.com/webcast/Play/46a8899c50914665b27d134db530bd421d>

AGENDA

- 10:00 – 10:05 am **Welcome**
Robyn Bent, RN, MS, CAPT, US Public Health Service
Office of the Center Director, Center for Drug Evaluation and Research, FDA
- 10:05 – 10:10 am **Opening Remarks**
Kendall Marcus, MD
Division of Dermatology and Dentistry, Center for Drug Evaluation and Research, FDA
- 10:10 – 10:20 am **Overview of FDA’s Patient-Focused Drug Development Initiative**
Theresa Mullin, PhD
Office of the Center Director, Center for Drug Evaluation and Research, FDA
- 10:20 – 10:30 am **Background on Vitiligo**
Brenda Carr, MD
Division of Dermatology and Dentistry, Center for Drug Evaluation and Research, FDA
- 10:30 – 10:40 am **Overview of Discussion Format**
Robyn Bent, RN, MS, CAPT, US Public Health Service
Office of the Center Director, Center for Drug Evaluation and Research, FDA
- 10:40 – 11:10 am **Topic 1: Health Effects and Daily Impacts**
A panel of patients and patient representatives will provide comments to start the discussion on health effects and daily impacts of vitiligo.
- 11:10 am – 12:15 pm **Large-Group Facilitated Discussion on Topic 1**
Patients and patient representatives in the audience are invited to add to the dialogue.
- 12:15 – 12:45 pm **Break**
- 12:45 – 1:15 pm **Topic 2: Current Approaches to Treatment**
Patient perspectives on current approaches to treatment for vitiligo. A panel of patients and patient representatives will provide comments to start the discussion.
- 1:15 – 2:20 pm **Large-Group Facilitated Discussion on Topic 2**
Patients or patient representatives in the audience are invited to add to the dialogue.
- 2:20 – 2:25 pm **Closing Remarks**
Kendall Marcus, MD
Division of Dermatology and Dentistry, Center for Drug Evaluation and Research, FDA

DISCUSSION QUESTIONS

Topic 1: Health effects and daily impacts that matter most to patients

1. Which **aspects** of vitiligo have the most significant impact on your life? (Examples may include depigmentation, itching, sensitivity to sunlight, etc.)
2. 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 vitiligo? (Examples of activities may include participating in social events, sports, being outside in the sunlight, etc.)
 - a. How does your vitiligo and its impacts affect your daily life on the **best days**? On the **worst days**?
3. How has your vitiligo **changed over time**?
 - a. How has your vitiligo changed from childhood to adulthood (such as vitiligo severity, disease acceptance)?
 - b. Would you define your vitiligo today as being well-managed?
4. What **worries you** most about your vitiligo?
 - a. Is there a particular body area affected by vitiligo (such as face, body) that is of most concern to you?

Topic 2: Patients' perspectives on current approaches to treatment

1. **What are you currently doing** to help treat your vitiligo? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification.)
 - a. How has your treatment regimen changed over time, and why?
2. **How well** does your current treatment regimen treat the most significant aspects of your vitiligo? For example, how well do your treatments improve your ability to do specific activities?
3. What are the most significant **downsides to your current treatments**, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, depigmentation of affected area is more noticeable, going to the hospital for treatment, etc.)
4. Assuming there is no complete cure for your vitiligo, what specific things would you look for in an **ideal treatment** for your vitiligo?
 - a. Is there a particular body area affected by vitiligo (such as face, body) that you would prioritize for treatment?
5. What factors do you consider when making decisions about selecting a course of treatment?

SUBMIT A COMMENT TO THE PUBLIC DOCKET

We encourage participants to submit written comments to the public docket by May 10, 2021: <https://beta.regulations.gov/document/FDA-2020-N-0255-0054> or visit www.regulations.gov and search for FDA-2020-N-0255-0054.