DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0255]

Patient-Focused Drug Development for Vitiligo; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: In the **Federal Register** notice published on March 19, 2020, the Food and Drug Administration (FDA, Agency, or we) announced the cancellation of the public meeting entitled ''Patient-Focused Drug Development for Vitiligo'' originally scheduled to occur on March 30, 2020, as announced in the **Federal Register** on February 12, 2020. FDA is announcing a new date for the meeting, to occur in a virtual format. The purpose of the public meeting is to allow FDA to obtain patient perspectives on the impact of vitiligo on daily life, patient views on treatment approaches, and decision factors considered when selecting a treatment.

DATES: The public meeting will be held on March 8, 2021, from 10 a.m. to 2:30 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by May 10, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public meeting via an online conferencing platform.

You may submit comments as follows. The docket number to submit comments is FDA–2020–N–0255. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 10, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 10, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2020–N–0255 for ''Patient-Focused Drug Development for Vitiligo; 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: Shannon Cole, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–9208, *PatientFocused@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 19, 2020, FDA announced in the **Federal Register** (85 FR 15789) the cancellation of the meeting entitled ''Patient-Focused Drug Development for Vitiligo,'' originally scheduled to occur on March 30, 2020, as announced in the **Federal Register** on February 12, 2020 (85 FR 8004). The meeting has been rescheduled in a virtual format.

This meeting will provide FDA with the opportunity to obtain patient and patient representative input on the aspects of vitiligo, including how it affects daily life, what matters most to patients, and on current approaches to treating vitiligo. Vitiligo is an autoimmune disease that causes the loss of skin color. The loss of color can affect skin, hair, and other areas of the body. The area affected by color loss can range in individual patients from small discrete areas to near total involvement. Although there is no cure or FDA-approved treatment for repigmentation, there are available therapies, such as prescription medications or non-drug therapies, which may be used to manage

aspects of vitiligo. FDA is interested in patients' (including adult and pediatric patients) perspectives on: (1) The impact of their vitiligo; (2) treatment approaches; and (3) decision factors considered when selecting a treatment.

The questions that will be asked of patients and patient representatives at the meeting are listed in the following section and organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This discussion will be followed by a facilitated discussion inviting comments from other patients and patient representatives. In addition to input generated through this public meeting, FDA is interested in receiving patient and patient representative input addressing these questions 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 following questions as much as possible from the patient's 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/public-meeting-patient-focused-drug-development-vitiligo-03082021-03082021.*

II. Topics for Discussion at the Public Meeting

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, playing 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, hands, limbs) 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, hospital treatments, 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, hands, limbs) that you would prioritize for treatment?

5. What factors do you consider when making decisions about selecting a course of treatment?

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting via webcast must register online at *https://vitiligopfdd.eventbrite.com.* Persons without access to the internet can call 301–796–9208 to register. Contact information provided during registration will remain confidential and will only be used to send meeting updates to participants.

Registration for this virtual event is free, although there may be limited space for attendance based on bandwidth availability. Webcast information will be provided upon completion of registration. Closed captioning will be provided. Please check the meeting website for the latest information: *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-vitiligo-03082021-03082021.*

If you need special accommodations due to a disability, please contact Shannon Cole (see **FOR FURTHER INFORMATION CONTACT**) no later than March 1, 2021.

Streaming Webcast of the Public Meeting: This public meeting will be streamed via webcast only. The recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting. To register for the webcast, please visit *https://vitiligopfdd.eventbrite.com.* The webcast can also be accessed via: *https://fda.yorkcast.com/webcast/Play/46a8899c50914665b27d134db530bd421d.* Simply click on the link and hit the ''play'' button and it will start. The webcast link will be activated 30 minutes prior to the start of the meeting.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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 meeting website at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-vitiligo-03082021-03082021.*

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4337]

Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; 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 or Agency) is announcing the following virtual public meeting entitled ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' The purpose of the virtual public meeting and the request for comments is to fulfill FDA's commitment to seek stakeholder input related to data standards and the electronic submission system's past performance, future targets, emerging industry needs, and technology initiatives. FDA will use the information from the public meeting as