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.

[FR Doc. 2021–00832 Filed 1–14–21; 8:45 am]

BILLING CODE 4164–01–P

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

well as from comments submitted to the docket to provide input into data standards initiatives, the FDA Information Technology (IT) Strategic Plan, and electronic submissions gateway target timeframes.

DATES: The public meeting will be held on April 7, 2021, from 9 a.m. to 1 p.m. Eastern Time and will take place virtually, held by webcast only. Submit either electronic or written comments on this public meeting by March 7, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Registration to attend the meeting and other information can be found at *https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-information-technology-goals-and-progress.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 7, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 7, 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–2018–N–4337 for ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' 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 laws. 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: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 240–402–6511, *bryan.spells@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, *stephen.ripley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to achieve the long-term goal of improving the predictability and consistency of the electronic submission process and enhancing transparency and accountability of FDA information technology-related activities. In the document containing the performance goals and procedures for the Prescription Drug User Fee Act (PDUFA) reauthorization for fiscal years 2018 through 2022 (the PDUFA VI commitment letter), FDA agreed to hold annual public meetings to seek stakeholder input related to electronic submissions and data standards to inform the FDA IT Strategic Plan and published targets. The PDUFA VI commitment letter outlines FDA's performance goals and procedures under the PDUFA program for the years 2018 through 2022. The PDUFA VI commitment letter can be found at *https://www.fda.gov/media/99140/download.*

FDA will consider all comments made at this meeting or received through the docket (see **ADDRESSES**).

II. Participating at the Public Meeting

Registration: To register to attend ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards,'' please visit the following website to register: *https://www.eventbrite.com/e/pdufa-vi-2021-public-meeting-on-electronic-submissions-and-data-standards-tickets-126816546705.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. A draft agenda will be posted approximately 1 month prior to the meeting.

Opportunity for Public Comment: Those who register online by March 7,

2021, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by March 7, 2021, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by March 21, 2021. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be held via Adobe Connect webcast: *https://collaboration.fda.gov/pdufavify21/.*

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/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00831 Filed 1–14–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

RIN 0991–ZA52

Making Permanent Regulatory Flexibilities Provided During the COVID–19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; request for information.

SUMMARY: To provide Americans with expanded access to certain medical devices to respond to the COVID–19 Public Health Emergency, FDA issued guidance documents providing numerous regulatory flexibilities, including a temporary waiver of premarket notification requirements under section 510(k) of the Food, Drug, and Cosmetic Act. For seven class I devices for which 510(k) premarket review as temporarily waived during the PHE, the Department of Health and Human Services is permanently exempting those seven (7) class I devices from the 510(k) requirement and is also proposing to exempt an additional 83 class II devices and 1 unclassified device class from the 510(k) requirement, for which premarket review had also been waived during the PHE. The Department is soliciting the public's views on whether premarket review should be permanently waived for some or all of these 83 devices and views on ways to improve the 510(k) premarket notification program.

DATES: Part III.A of this Notice shall be effective immediately on publication in the **Federal Register**. To be considered, responses and comments related to Part III.B of this Notice must be received electronically, within sixty days of publication in the **Federal Register** as provided below. The Department will consider information submitted by the public in response to Part IV of this Notice on a rolling basis, and until further notice.

ADDRESSES: You may submit comments through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Comments must be identified by 0991–ZA52. Because of staff and resource limitations, all comments must be submitted electronically to *www.regulations.gov.* Follow the ''Submit a comment'' instructions.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.* Follow the search instructions on that website to view the public comments.

FOR FURTHER INFORMATION CONTACT: Dan Barry, 200 Independence Ave. SW, Washington, DC 20201; or by email at *daniel.barry@hhs.gov;* or by telephone at 1–877–696–6775.

SUPPLEMENTARY INFORMATION: The Administration is committed to creating a data-based regulatory process that appropriately balances benefits and costs. Consistent with the President's executive order on COVID–19 regulatory flexibilities, and Congress' direction in the 21st Century Cures Act, the Department is issuing this Notice to permanently exempt or proposing to permanently exempt certain class I and class II medical devices from the premarket notification requirement in section 510(k) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 360(k). Under this notice, the Department is immediately making permanent the exemption of 7 class I device classes from the section 510(k) requirement and proposes to exempt an additional 84 class II and unclassified device classes from the same requirement on a permanent basis. These 91 devices were all subject a 510(k) waiving during the PHE.

I. Background

A. Statutory Framework

Under the Food, Drug, and Cosmetic Act (FD&C Act), medical devices are placed ''in three categories based on the risk that they pose to the public.'' [1] Class I devices, products ''that present no unreasonable risk of illness or injury,'' [2] are subject to general controls. FD&C Act 513(a)(1)(A), 21 U.S.C.

[1] *Medtronic, Inc.* v. *Lohr,* 518 U.S. 470, 476 (1996).

[2] *Id.* at 476–77.