I. Background on Patient-Focused Drug Development

FDA has selected sickle cell disease to be the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients’ perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA’s performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on sickle cell disease and on current approaches to treatment. Approximately 100,000 people in the United States, and millions of people worldwide, have sickle cell disease. Sickle cell disease is an inherited red blood cell disorder resulting from a mutation in the beta globin gene. Red blood cells are more prone to an abnormal shape and rigidity, causing multi-organ damage over time. Some of the effects of sickle cell disease are painful crises, increased risk of infections, stroke, pulmonary hypertension, acute chest syndrome, recurrent priapism, gallstones, and kidney dysfunction.

Therapies to prevent the complications of sickle cell disease are limited and can include prescription medications and blood transfusions. Bone marrow transplantation is an option for some patients. Other therapies, such as pain medications, antibiotics, supplemental oxygen, and vitamin supplements, are used to manage specific health effects of the disease. New approaches to treating sickle cell disease or preventing its complications are being explored, including new medications, advances in transplantation, and gene therapies. FDA is interested in obtaining a better understanding of patients’ perspectives on sickle cell disease, including the symptoms that matter most to patients, limitations to current treatment approaches, opportunities for new treatment approaches, and specific considerations regarding sickle cell disease in pediatric patients.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input gathered through this public meeting, FDA is interested in receiving patient input addressing these questions.
through written comments that can be submitted to the public docket (see ADDRESSES). When submitting comments to the docket, please provide some context to your comment by indicating whether you are an adolescent or young adult, or older adult. If you are commenting on behalf of a child or other loved one who has sickle cell disease, please indicate that and answer the following questions as much as possible from the patient’s perspective.

**Topic 1: The Effects of Sickle Cell Disease That Matter Most to You**

1. Of all of the ways that sickle cell disease affects your health, which one to three effects have the greatest impact on your life? (Examples may include pain crises, breathing problems, difficulty concentrating, tiredness, infections, and others.)

2. How does sickle cell disease affect your life on an “average” day?
   a. Are there activities that you cannot do at all or as well as you would like on these “average” days?
   b. What are the biggest problems with these treatments? (Examples may include side effects of medicine, going to the hospital for treatment, frequent blood tests, etc.)
   c. How do these problems affect your daily life?

3. Besides prescription medications, what else do you do to prevent or treat any negative effects of your sickle cell disease? Please describe any medications purchased at a store without a prescription, home remedies, diet changes, massages, or other therapies.

4. What specific parts of your sickle cell disease do these treatments address?
   a. How well do these treatments work for you?
   b. What are the biggest problems with these treatments?

5. What specific concerns do you have about sickle cell disease? Please describe any serious risks, and other things.
   a. What specific parts of your sickle cell disease is, how well current treatments are working for you, your concern about serious risks, and other things.

**B. Meeting Attendance and/or Participation**

If you wish to attend this meeting, visit https://patientfocusedsicklecell.eventbrite.com. Please register by January 27, 2014. Those who are unable to attend the meeting in person can register to participate in a live Webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the Webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Graham Thompson (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will also be asked to send a brief summary of responses to the topic questions to PatientFocused@fda.hhs.gov. Panelists will be notified of their selection soon after the close of registration on January 27, 2014. FDA will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Interested members of the public, including those who attend the meeting in person or through the Webcast, are invited to provide electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see ADDRESSES). Comments may be submitted until April 8, 2014.

Dated: October 31, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–1285]

Smith Miller and Patch Inc. et al.; Proposal to Withdraw Approval of 14 New Drug Applications; Opportunity for a Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity to request a hearing on the Agency’s proposal to withdraw approval of 14 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

**DATES:** Submit written requests for a hearing by December 6, 2013; submit data and information in support of the hearing request by January 6, 2014.

**ADDRESSES:** Identify your requests for a hearing, supporting data, and other comments with Docket No. FDA–2013–N–1285, and submit this information to the Division of Dockets Management (HFA–305), Food and Drug