



# Public Meeting on Patient-Focused Drug Development for Psoriasis

March 17, 2016



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9:00 – 10:00 am	<b>Registration</b>
10:00 – 10:05 am	<b>Welcome</b> Sara Eggers, PhD <i>Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA</i>
10:05 – 10:10 am	<b>Opening Remarks</b> Kendall Marcus, MD <i>Director, Division of Dermatology and Dental Products (DDDP), CDER, FDA</i>
10:10 – 10:20 am	<b>Overview of FDA’s Patient-Focused Drug Development Initiative</b> Theresa Mullin, PhD <i>Director, OSP, CDER, FDA</i>
10:20 – 10:35 am	<b>An Overview of Psoriasis and Available Treatments</b> Jane Liedtka, MD <i>DDDP, CDER, FDA</i>
10:35 – 10:40 am	<b>The Road from PFDD Meetings to Clinical Trial Endpoints</b> Yasmin Choudhry, MD <i>Clinical Outcomes Assessment (COA) Staff, Office of New Drugs (OND), CDER, FDA</i>
10:40 – 10:45 am	<b>Overview of Discussion Format</b> Sara Eggers, PhD <i>OSP, CDER, FDA</i>
10:45 – 11:15 am	<b>Panel #1 Discussion on Topic 1</b> Topic 1: Disease symptoms and daily impacts that matter most to patient. A panel of patients will provide comments to start the discussion.
11:15 – 12:30 pm	<b>Large-Group Facilitated Discussion: Topic 1</b> Patients and patient representatives in the audience will be invited to add to the dialogue.
12:30 – 1:30 pm	<b>Lunch</b>
1:30 – 1:35 pm	<b>Afternoon Welcome</b> Sara Eggers, PhD <i>OSP, CDER, FDA</i>
1:35 – 2:05 pm	<b>Panel #2 Discussion on Topic 2</b> Topic 2: Patient perspectives on current approaches to treating psoriasis. A panel of patients will provide comments to start the discussion
2:05 – 3:20 pm	<b>Large-Group Facilitated Discussion: Topic 2</b> Patients and patient representatives in the audience will be invited to add to the dialogue.
3:20 – 3:50 pm	<b>Open Public Comment</b>
3:50 – 4:00 pm	<b>Closing Remarks</b> Kendall Marcus, MD <i>DDDP, CDER, FDA</i>

## Discussion Questions

### Topic 1: Disease symptoms and daily impacts that matter most to patients

- 1) Of all the symptoms that you experience because of your condition, which 1-3 symptoms have the most significant impact on your life? (Examples may include red, thickened, scaling skin, itching, burning or soreness, 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 condition? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
- 3) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
- 4) How have your condition and its symptoms changed over time?
  - a) Would you define your condition today as being well managed?
- 5) What worries you most about your condition?

### Topic 2: Patients' perspectives on current approaches to treatment

- 1) What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, phototherapy, 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 control your condition?
  - a) How well do your treatments address specific skin symptoms? Which symptoms are not addressed as well?
  - b) How well have these treatments worked for you as your condition has changed over time?
- 3) What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include going to the hospital or clinic for treatment, time devoted to treatment, etc.)
- 4) Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?
  - a) What would you consider to be a meaningful improvement (for example symptom improvements or functional improvements) in your condition that a treatment could provide?
- 5) What factors do you take into account when making decisions about selecting a course of treatment?
  - a) What information on the potential benefits of these treatments factors most into your decision?
  - b) How do you weigh the potential benefits of these treatments versus the common side effects of the treatments? (Common side effects could include headache, nausea, injection site reactions)
  - c) How do you weigh potential benefits of these treatments versus the less common but serious risks associated with the treatments? (Examples of less common but serious risks are infections, cancer, liver damage, kidney damage, birth defects, blood disorders, etc.)

## Docket Information

We encourage you to submit your written comments to the docket by May 17, 2016:

<http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-4166-0001> or go to [www.regulations.gov](http://www.regulations.gov) and search for: **psoriasis patient-focused drug development**.