



**Public Meeting on
Female Sexual Dysfunction
Patient-Focused Drug Development**



October 27, 2014

11:00 – 12:00 pm	Registration
12:00 – 12:05 pm	Welcome
12:05 – 12:10 pm	Opening Remarks Audrey Gassman, M.D. <i>Deputy Director, Division of Bone, Reproductive and Urologic Products (DBRUP) Office of Drug Evaluation 3 (ODE3), Office of New Drugs (OND), CDER, FDA</i>
12:10 – 12:20 pm	Overview of FDA’s Patient-Focused Drug Development Initiative Theresa Mullin, PhD <i>Director, Office of Strategic Programs (OSP), CDER, FDA</i>
12:20 – 12:35 pm	Background on Disease Area and Treatment Christina Chang, M.D., M.P.H. <i>Clinical Team Leader, DBRUP, ODE3, OND, CDER, FDA</i>
12:35 – 12:45 pm	Overview of Discussion Format Sara Eggers, Ph.D. <i>OSP, CDER, FDA</i>
12:45 – 1:15 pm	Panel #1 Comments: <u>Topic 1</u> Disease symptoms and daily impacts that matter most to patients. A panel of patients and patient representatives will provide comments to start the discussion.
1:15 – 2:15 pm	Large-Group Facilitated Discussion: <u>Topic 1</u> Patients and patient representatives in the audience are invited to add to the dialogue.
2:15 – 2:30 pm	Break
2:30 – 3:00 pm	Panel #2 Comments: <u>Topic 2</u> Patient perspectives on current approaches to treating female sexual interest/arousal disorder. A panel of patients and patient representatives will provide comments to start the discussion.
3:00 – 3:50 pm	Large-Group Facilitated Discussion: <u>Topic 2</u> Patients and patient representatives in the audience are invited to add to the dialogue.
3:50 – 4:20 pm	Open Public Comment
4:20 – 4:30 pm	Closing Remarks RADM (retired) Sandra Kweder, M.D. <i>Deputy Director, OND, CDER, FDA</i>

Discussion Questions

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

- 1) Have you ever received a diagnosis from a healthcare provider of sexual interest/arousal disorder, hypoactive sexual desire disorder, or sexual arousal disorder?
 - a) How was the diagnosis made? For example, what type of healthcare provider made the diagnosis? Were any tests or questionnaires used to help make the diagnosis?
- 2) Of all the symptoms that you experience because of your condition, which **1-3 symptoms** have the most significant impact on your life? Please describe each symptom in detail, including how this symptom specifically affects your sexual experiences.
- 3) Do your symptoms wax and wane over time? For example, do you have better days and worse days? If your symptoms wax and wane, please answer the following questions:
 - a) Which symptoms vary the most, and in what ways?
 - b) How do your symptoms and their negative impacts on your sexual experiences compare between your “best days” and your “worst days”?
 - c) Do the changes in your symptoms typically happen over a period of minutes, hours, days, weeks, or months?
- 4) If you were asked today to accurately rate how good or how bad your symptoms have been over time, would you be able to accurately remember how your symptoms felt one day ago? Over the past 3 days? Over the past week? Over the past 2 weeks? Over the past 3 weeks? Over the past month? Is there anything else that you believe makes your symptoms better? Is there anything that you believe makes your symptoms worse? For example, menstruation, stress, etc.
- 5) Overall, have you experienced your condition and its symptoms getting progressively worse, improving, or remaining stable over the past few years?
- 6) What worries you most about your condition?

Topic 2: Patient perspectives on current approaches to treat FSIAD

- 1) What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, physical or other therapies, support groups, and lifestyle changes.)
- 2) How well do your current treatments specifically treat the most significant symptoms of your condition?
- 3) How well have your treatments improved your sexual experience?
- 4) How has your treatment regimen changed over time, and why?
- 5) Are there any downsides to the treatments you have used? (Examples of downsides may include bothersome side effects, difficulty identifying appropriate healthcare providers, etc.)
- 6) What specific things would you look for in an ideal treatment for your condition? For example, which symptom would you most like a treatment to target and what would you consider to be a meaningful improvement in this symptom?