U.S. FOOD & DRUG ADMINISTRATION

# Public Meeting on Patient-Focused Drug Development for Autism

May 4, 2017

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| 12:00 – 1:00 pm | **Registration** |
| 1:00 – 1:05 pm | **Welcome**<br>Sara Eggers, PhD<br>*Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA* |
| 1:05 – 1:10 pm | **Opening Remarks**<br>Ellis Unger, MD<br>*Director, Office of Drug Evaluation 1 (ODE 1), Office of New Drugs (OND), CDER, FDA* |
| 1:10 – 1:20 pm | **Overview of FDA's Patient-Focused Drug Development Initiative**<br>Pujita Vaidya, MPH<br>*OSP, CDER, FDA* |
| 1:20 – 1:30 pm | **Overview of Autism and Current Treatment Options**<br>Tiffany Farchione, MD<br>*Deputy Director, Division of Psychiatry Products (DPP), OND, CDER, FDA* |
| 1:30 – 1:35 pm | **The Road from PFDD Meetings to Clinical Trial Endpoints**<br>Ebony Dashiell-Aje, PhD<br>*Clinical Outcome Assessments Staff, OND, CDER, FDA* |
| 1:35 – 1:40 pm | **Overview of Discussion Format**<br>Sara Eggers, PhD<br>*OSP, CDER, FDA* |
| 1:40 – 2:00 pm | **Panel #1 Discussion on Topic 1: Health Effects and Daily Impacts of Autism**<br>Topic 1: A panel of individuals and caregivers will provide comments to start the discussion on significant health effects and daily impacts of autism. |
| 2:00 – 3:00 pm | **Large-Group Facilitated Discussion: Topic 1**<br>Individuals and caregivers in the audience will be invited to add to the dialogue. |
| 3:00 – 3:10 pm | **Break** |
| 3:10 – 3:30 pm | **Panel #2 Discussion on Topic 2: Current Approaches to Treatment**<br>Topic 2: A panel of individuals and caregivers will provide comments to start the discussion on current approaches to treating autism. |
| 3:30 – 4:25 pm | **Large-Group Facilitated Discussion: Topic 2**<br>Individuals and caregivers in the audience will be invited to add to the dialogue. |
| 4:25 – 4:55 pm | **Open Public Comment** |
| 4:55 – 5:00 pm | **Closing Remarks**<br>Mitchell Mathis, MD<br>*Director, DPP, OND, CDER, FDA* |

**Docket Information:** We encourage you to submit your written comments to the docket by July 5, 2017: https://www.federalregister.gov/d/2017-04229 or go to www.regulations.gov and search for: **autism patient-focused drug development.**