



**A Scientific Workshop on
Labeling “Low” Dose Estrogen-Alone Products
For Symptoms of Vulvar Vaginal Atrophy (VVA)**



November 10, 2015

- 7:00 - 8:00 am **Registration**
- 8:30 am **Welcome**
Audrey Gassman, M.D.
Deputy Director
Division of Bone, Reproductive and Urologic Products (DBRUP)
Office of Drug Evaluation III (ODE III)
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
FDA
- 8:40 am **Background and Meeting Objectives**
Shelley R. Slaughter, M.D., Ph.D.
Medical Officer Team Leader
DBRUP, ODE III, OND
CDER, FDA
- 8:50 am **Estrogen-Alone Class Labeling: Regulatory History and Implementation**
Theresa van der Vlugt, M.D.
Medical Officer
DBRUP, ODE III, OND
CDER, FDA
- 9:20 am **Epidemiology of Thromboembolism in Postmenopausal Women**
Aneel A. Ashrani, M.D., M.S.
Assistant Professor of Medicine
Division of Hematology
Department of Internal Medicine
Mayo Clinic College of Medicine
- 9:50 am **Lower-dose Estrogen-Alone Products and Thrombotic/Thromboembolic Events –
FDA Perspective**
Theresa van der Vlugt, M.D.
Medical Officer
DBRUP, ODE III, OND
CDER, FDA
- And
- Joel Weissfeld, M.D., M.P.H.
Medical Officer
Division of Epidemiology (DEPI I)
Office of Surveillance and Epidemiology, CDER, FDA

- 10:30 am **Clarifying Questions**
- 10:40 am **Break**
- 10:55 am **Pharmacokinetics and Systemic Estrogen Exposure with Vaginal Estrogen Products**
LaiMing Lee, Ph.D.
Clinical Pharmacologist
Division of Clinical Pharmacology III
Office of Clinical Pharmacology
CDER FDA
- 11:20 am **Potential Utility of Hemostatic Pharmacodynamic Markers for Monitoring Thromboembolic Risks of Estrogen-Alone Products**
Jihong Shon, Ph.D.
Senior Staff Fellow
Division of Clinical Pharmacology III
Office of Clinical Pharmacology
CDER FDA
- 11:40 am **Estrogen Therapy and Mechanism of Thrombosis – Are There Useful Pharmacodynamics Markers**
Per Morten Sandset, M.D., Ph.D.
Research and Innovation Director, Senior Consultant, Professor, M.D., Ph.D.
Southeastern Norway Health Authority
Oslo University Hospital and University of Oslo
Research Institute of Internal Medicine and Department of Haematology
- 12:10 pm **Clarifying Questions**
- 12:20 pm **Lunch**
- 1:20 pm **Impact of Estrogen-Alone Boxed Warnings on Patient Behavior**
Audrey Gassman, M.D.
Deputy Director
DBRUP, ODE III, OND
CDER, FDA
- 1:30 pm **Open Public Comment Session**
- 2:30 pm **Charge to the Panel**
Shelley R. Slaughter, M.D., Ph.D.
Medical Officer Team Leader
DBRUP, ODE III, OND
CDER, FDA
- 2:40 pm **Panel Discussion – Part 1**
- 3:40 pm **Break**
- 3:50 pm **Panel Discussion – Part 2**

4:50 pm

Closing Remarks

Shelley R. Slaughter, M.D., Ph.D.
Medical Officer Team Leader
DBRUP, ODE III, OND
CDER, FDA

5:00 pm

Adjourn