

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Oncologic Drugs Advisory Committee (ODAC) Meeting***  
Tommy Douglas Conference Center  
10000 New Hampshire Avenue, Silver Spring, Maryland 20903  
September 14, 2016

**AGENDA**

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*The committee will discuss new drug application 208714, apaziquone for intravesical instillation, application submitted by Spectrum Pharmaceuticals, Inc. The proposed indication (use) for this product is for immediate intravesical instillation post-transurethral resection of bladder tumors in patients with non-muscle invasive bladder cancer.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Bruce J. Roth, MD</b> Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	<b>Lauren Tesh, PharmD, BCPS</b> Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	<b>Chana Weinstock, MD</b> Medical Officer, Genitourinary Cancers Team Division of Oncology Products 1 (DOP1) Office of Hematology & Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	<b>GUEST SPEAKER PRESENTATION</b>	
	Overview of Diagnosis and Management of Non-Muscle Invasive Bladder Cancer	<b>Seth P. Lerner, MD, FACS</b> Professor, Scott Department of Urology Beth and Dave Swalm Chair in Urologic Oncology Director of Urologic Oncology Director of the Multidisciplinary Bladder Cancer Program Baylor College of Medicine Medical Center Houston, Texas
8:30 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Spectrum Pharmaceuticals, Inc.</b>
	Introduction	<b>Anil K. Hiteshi, RAC</b> Global Regulatory Affairs Spectrum Pharmaceuticals, Inc.
	Post-Operative Intravesical Therapy	<b>Neal Shore, MD</b> Medical Director Carolina Urologic Research Center

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September 12, 2016

**AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

Clinical Efficacy and Safety

**Gajanan Bhat, PhD**

Vice President, Biostatistics, Data Management  
and Medical Writing  
Spectrum Pharmaceuticals, Inc.

Benefit-Risk and Clinical Utility of  
Apaziquone

**Alfred Witjes, MD**

Professor of Urologic Oncology  
Radboud University Nijmegen Medical Centre

Clinical Perspective

**Mark Soloway, MD**

Chief of Urological Oncology  
Memorial Cancer Institute, Miami

Concluding Remarks

**Rajesh Shrotriya, MD**

Chairman and Chief Executive Officer  
Spectrum Pharmaceuticals, Inc.

9:15 a.m.

**FDA PRESENTATIONS**

NDA 208714 - Apaziquone

**Gwynn Ison, MD**

Medical Officer  
DOP1, OHOP, OND, CDER, FDA

FDA Statistical Analysis

**Erik Bloomquist, PhD**

Statistical Reviewer  
Division of Biometrics V (DBV)  
Office of Biometrics (OB)  
Office of Translational Sciences (OTS)  
CDER, FDA

10:00 a.m. Clarifying Questions to the Presenters

10:30 a.m. **BREAK**

10:45 a.m. Open Public Hearing

11:45 a.m. Questions to the Committee/Committee Discussion

1:00 p.m. **ADJOURNMENT**