Information will be presented to gauge investigator interest in exploring potential pediatric development plans for three products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) GANETESPIB, application submitted by Synta Pharmaceuticals Corp. (2) Etipirinotecan, application submitted by Nektar Therapeutics, and (3) RO5503781, application submitted by Hoffmann-La Roche, Inc.

8:00 a.m. Call to Order
Introduction of Subcommittee

Alberto Pappo, MD
Acting Chairperson, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC)

8:05 a.m. Conflict of Interest Statement

Caleb Briggs, PharmD
Designated Federal Officer, pedsODAC

8:10 a.m. Introductory Remarks

Gregory Reaman, MD
Associate Director for Oncology Sciences, Office of Hematology and Oncology Products (OHOP), Office of New Drugs (OND), CDER, FDA

8:15 a.m. SESSION 1: GANETESPIB – SYNTA PHARMACEUTICALS CORP.

Conflict of Interest Statement

Caleb Briggs, PharmD

Announcement of Change to Participants

Alberto Pappo, MD

8:20 a.m. SPONSOR PRESENTATIONS

Synta Pharmaceuticals Corp.

Ganetespib and Hsp90 Inhibition

Vujo Vukovic, MD, PhD
Chief Medical Officer
Synta Pharmaceuticals Corp.

SARC 023 Study

AeRang Kim, MD, PhD
Assistant Professor of Pediatrics
The George Washington School of Medicine

8:40 a.m. Clarifying Questions from Subcommittee
AGENDA (cont.)

8:55 a.m. Open Public Hearing

9:15 a.m. Questions to the Subcommittee and Subcommittee Discussion

10:15 a.m. BREAK

10:30 a.m. SESSION 2: ETIRINOTECAN PEGOL – NEKTAR THERAPEUTICS

Conflict of Interest Statement Caleb Briggs, PharmD
Announcement of Change to Participants Alberto Pappo, MD

10:35 a.m. SPONSOR PRESENTATIONS Nektar Therapeutics

Etitrnotecan Pegol: Nonclinical Pharmacology, Pharmacokinetics and Clinical Development Carla Di Fonzo, PhD
Vice President, Drug Development and Regulatory Affairs
Nektar Therapeutics

Alison L. Hannah, MD
Consultant to Nektar Therapeutics

10:55 a.m. Clarifying Questions from Subcommittee

11:10 a.m. Open Public Hearing

11:30 a.m. Questions to the Subcommittee and Subcommittee Discussion

12:30 p.m. LUNCH

1:30 p.m. SESSION 3: RO5503781 – HOFFMAN-LA ROCHE, INC.

Conflict of Interest Statement Caleb Briggs, PharmD
Announcement of Change to Participants Alberto Pappo, MD

1:35 p.m. SPONSOR PRESENTATION Hoffman-La Roche, Inc.

The MDM2 Antagonist RO5503781 Gwen Nichols, MD
Site Head, Translational Medicine Oncology
Roche Pharmaceutical Research and Early Development

1:55 p.m. Clarifying Questions from Subcommittee
AGENDA (cont.)

2:10 p.m.  Open Public Hearing

2:30 p.m.  Questions to the Subcommittee and Subcommittee Discussion

3:30 p.m.  ADJOURNMENT