

**Creating an Alternative Approval Pathway for Certain Drugs Intended to Address
Unmet Medical Need
Part 15 Public Hearing**

February 4, 2013

**FDA White Oak Campus
10903 New Hampshire Ave, Building 31, Room 1503
Silver Spring, Maryland 20993**

Each speaker will have 10 minutes for their presentation. There will be 5 minutes following each presentation to offer an opportunity for the panel to ask clarifying questions.

February 4, 2013 Presentations

9:00 – 9:10 am

Presiding Officer Opening Remarks

**Rachel Sherman, MD, MPH
Associate Director for Medical Policy,
Center for Drug Evaluation and Research**

9:11 – 9:21 am (9:21– 9:26 am)

Jeffrey Spaeder, *Quintiles*

9:27 – 9:37am (9:37– 9:42 am)

Roger Echols, *Infectious Disease Drug Development Consulting, LLC*

9:43 – 9:53 am (9:53– 9:58 am)

Rebecca O'Connor, *Parkinson's Action Network*

9:59 – 10:09 am (10:09– 10:14 am)

**Jeffrey Stein, *Antibiotics Working Group (AWG),
Trius Therapeutics***

BREAK

10:14 – 10:30 am

10:31 – 10:41 am (10:41– 10:46 am)

Robert Guidos, *Infectious Diseases Society of America (IDSA)*

10:47 – 10:57 am (10:57– 11:02 am)

Paul Huckle, *GlaxoSmithKline (GSK)*

11:03 – 11:13 am (11:13– 11:18 am)

Jennifer A. Jackson, *Cubist Pharmaceuticals, Inc.*

11:19 – 11:29 am (11:29– 11:34 am)

John F. Crowley, *Amicus Therapeutics, Inc.*
John R. Kirk, *Amicus Therapeutics, Inc.*
Jayne C. Gershkowitz, *Amicus Therapeutics, Inc.*

11:35 – 11:45 am (11:45– 11:50 am)

John H. Powers, *George Washington University School of Medicine,*
University of Maryland School of Medicine

11:51 – 12:01 pm (12:01– 12:06 pm)

Nicole Mahoney, *The Pew Charitable Trusts*

LUNCH **Ala Carte items will be available for purchase on site**

12:07 am – 1:07 pm

1:08 – 1:18 pm (1:18– 1:23 pm)

Alan Solinger, *Pharmaceutical Product Development, LLC (PPD)*
Association of Clinical Research Organizations (ACRO)

1:24 – 1:34 pm (1:34– 1:39 pm)

Andrew J. Emmett, *Biotechnology Industry Organization (BIO)*

1:40 – 1:50 pm (1:50– 1:55 pm)

Jonathan Sackner-Bernstein, *NeoStem*

1:56 – 2:06 pm (2:06– 2:11 pm)

David Clifford, *PatientsLikeMe*

2:12 – 2:22 pm (2:22– 2:27 pm)

Roslyn Mannon, *American Society of Transplantation (AST),*
University of Alabama, Birmingham

2:28 – 2:38 pm (2:38– 2:43 pm)

James I. Healy, *Soffinova Ventures,*
National Venture Capital Association (NVCA)

BREAK

2:44 – 2:59 pm

3:00 – 3:10 pm (3:10– 3:15 pm)

Anthony Castaldo, *Hereditary Angioedema Association*

3:16 – 3:26 pm (3:26– 3:31 pm)

Jennifer Yttri, *National Research Center for Women & Families*

3:32 – 3:42 pm (3:42– 3:47 pm)

Mark Velleca, *Leukemia & Lymphoma Society*

Open Public Comments

3:47 – 4:50 pm

Closing remarks/Adjournment

4:50 – 5:00 pm

Please be advised that as soon as the transcript is available, it will be accessible at <http://www.fda.gov/Drugs/NewsEvents/ucm335680.htm>.

Written and electronic comments will be accepted until March 1, 2013. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.