

FDA Presentation of PDUFA IV Recommendations

Date Time Length	Subjects	Participants
<p>1/11/07 12:00 NOON to 1:00 PM 1 HOUR</p>	<p>Teleconference to brief on the Federal Register notice of a public meeting to discuss the proposed recommendations for the reauthorization of PDUFAQ&A Session</p>	<p>FDA: Theresa Mullin, OPPL Steven Galson, CDER Jane Axelrad, CDER Deborah Henderson, CDER John Jenkins, CDER Theresa Toigo, OER Patricia Kuntze, OER</p> <p>CONSUMERS AND PATIENTS: Jeff Allen, Jeff Coughlin, Friends of Cancer Research Amy Allina, National Women's Health Network Margaret Anderson, Cassie Banks, FasterCures Chatrane Birbal, American Psychiatric Association Jeff Bloom, Title II Community AIDS Action Network Susan Bowes, Lupus Foundation Mark Cohen, Government Accountability Project Edda Coleman, American Academy of Pediatrics Tony Corbo, Food and Water Watch Diane Dorman, National Organization for Rare Disorders Steve Gibson, ALS Association Susan Herold, Consumers Union Hara Jangochin, American Pharmaceutical Association Heidi Miller, National Research Center for Women & Families Sandi Morton, Academy of Managed Care Pharmacy Alison Rein, National Consumers League Lee Rucker, AARP Andrew Sperling, National Alliance on Mental Illness Scott Williams, Men's Health Network Mandy Wimmer, Parkinson Action Network Alicia Yass, Society for Womens Health Research Betsy Scott, Elizabeth Glaser Pediatric AIDS Foundation Cynthia Sperling, American Society of Clinical Oncology</p>
<p>2/8/07</p>	<p>Overview of the PDUFA IV Proposed</p>	<p>FDA:</p>

<p>11:30 AM to 1:30 PM 2 Hours</p>	<p>Recommendations:</p> <ul style="list-style-type: none"> • Background on the PDUFA Program & Sound Financial Footing • Pre-market Review • Post-market Safety • Advisory Review of Direct-to-Consumer Television Advertising <p>Q&A Session</p>	<p>Jane Alexrad, CDER Deborah Henderson, CDER John Jenkins, CDER Theresa Mullin, OPPL Patricia Kuntze, OER Theresa Toigo, OER</p> <p>CONSUMERS, PATIENTS, AND MEDICAL COMMUNITY: Lee Rucker, AARP Cynthia Farrell, Alliance for Aging Research James Baumberger, Marc Del Monte, American Academy of Pediatrics William Lang, American Association of Colleges of Pharmacy Susan Bishop, American Heart Association Marcie Bough, American Pharmacists Association Chartrane Birbal, American Psychiatric Association William Vaughan, Consumers Union Alexandra Bennewith, Cystic Fibrosis Foundation Roslyn Johnson, FasterCures Mark Cohen, Government Accountability Project Joseph Artie, Scott Williams, Men's Health Network Alison Rein, National Consumers League Yolanda Fleming, National Medical Association Diane Forman, Lakisa Carter, National Organization for Rare Disorders Renee Carter, Janet Phoenix, National Research Center for Women & Families Martha Nolan, Society for Women's Health Research Jeff Bloom, Title II AIDS Community National Network Paul Brown, US Public Interest Research Group</p>
<p>2/16/07 9:00 AM to 5:00 PM 8 Hours</p>	<p>Public Comment on FDA Proposed Recommendations for PDUFA IV</p>	<p>FDA: Andrew von Eschenbach, OC Janet Woodcock, OC Steven Galson, CDER Theresa Mullin, OPPL John Jenkins, CDER Malcolm Bertoni, OPPL Deborah Henderson, CDER Jane Axelrad, CDER</p> <p>PATIENTS: Perry Cohen, Parkinsons Pipeline</p>

		<p>Project Steve Gibson, ALS Association Amy Comstock, Parkinson's Action Network David Fassler, Mental Health America Jeff Allen, Friends of Cancer Research David Cavanaugh, Committee of Ten Thousand Andrew Sperling, National Alliance on Mental Illness Wilson DeCamp, Patient Ellen Liversidge, Alliance for Human Research Protection</p> <p>CONSUMERS: William Vaughan, Consumers Union Kim Witczak, Individual Consumer</p> <p>HEALTH PROFESSIONALS: Judith Cahill, Academy of Managed Care Pharmacy Brian Meyer, American Society of Health-Systems Pharmacists</p> <p>INDUSTRY: Alan Goldhammer, PhRMA Bridgette Ellis, Plasma Protein Therapeutics Association John Kamp, Coalition for Healthcare Communication Alan Kirschenbaum, on behalf of Council on Radionuclides and Radiopharmaceuticals Alison Lawton on behalf of Biotechnology Industry Organization Lili Ann Stiver, Drug Safety Institute</p> <p>OTHER PERSPECTIVE: Anthony Wisniewski, U.S. Chamber of Commerce</p>
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