

FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
*Joint Meeting of the Antiviral Drugs Advisory Committee and the
Nonprescription Drugs Advisory Committee*
Hilton Washington, DC/Rockville
October 29, 2008
Agenda

The committee will provide advice on types of studies and trial designs needed for an influenza antiviral MedKit for the treatment or prophylaxis of influenza during a pandemic and discuss publicly the proposed development program that would support an application for such a MedKit.

8:00 a.m. – 8:10 a.m.	Call to Order Introduction of Committee	Ian McGowan, M.D., Ph.D, FRCP. Chair, Antiviral Drugs Advisory Committee (AVAC)
8:10 a.m. – 8:15 a.m.	Conflict of Interest Statement	Paul Tran, RPh. Executive Secretary, AVAC
8:15 a.m. – 8:30 a.m.	Opening Remarks	Debra Birnkrant, M.D. Director, Division of Antiviral Products CDER, FDA
8:30 a.m. – 8:45 a.m.	Influenza Antiviral Drug Medkits: HHS Perspectives	John Tegeris, Ph.D. Senior Program Manager, Antiviral Drug Program Department of Health and Human Services (HHS)/BARDA
8:45 a.m. – 9:00 a.m.	Epidemiology of Seasonal and Pandemic Influenza	Tim Uyeki, M.D., M.P.H. Deputy Chief, Epidemiology and Prevention Branch Influenza Division Centers for Disease Control and Prevention
9:00 a.m. – 9:20 a.m.	A Perspective on Influenza Treatment and Prophylaxis	Frederick Hayden, M.D. Professor of Clinical Virology University of Virginia School of Medicine
9:20 a.m. – 9:40 a.m.	Influenza Resistance	Alexander Klimov, Ph.D Chief, Virus Surveillance and Diagnosis Branch Centers for Disease Control and Prevention
9:40 a.m. – 10:00 a.m.	Overview of Consumer Studies	CAPT Laura Shay R.N., M.S., C-ANP Social Science Analyst Division of Nonprescription Clinical Evaluation CDER, FDA
10:00 a.m. – 10:15 a.m.	Break	
10:15 a.m. – 10:45 a.m.	Relenza MedKit: Potential Use for Pandemic Influenza and Proposed Development Plan".	Judith Ng-Cashin, M.D. Global Clinical Vice President, Infectious Diseases Medicines Development Center GlaxoSmithKline
10:45 a.m. – 11:15 a.m.	TAMIFLU® MedKit for Pandemic Influenza	Michael McGuire, M.D. Vice President, Anti-Infectives Hoffmann-La Roche
11:15 a.m. – 11:45 a.m.	Clarifying Questions for the Sponsors	

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11:45 a.m. – 12:30 p.m.	Presentations from Associations	NACCHO, AAFP, IDSA, AMA, AAP, ASHP, APhA, ASTHO
11:45 a.m. – 11: 50 a.m.	Home stockpiling; Who benefits?	Brit Oiulfstad, DVM, M.P.H. National Association of County and City Health Officials (NAACHO)
11:50 a.m. – 11:55 a.m.	AAFP Viewpoint	Doug Campos-Outcalt, M.D., M.P.A. American Academy of Family Physicians (AAFP)
11:55 a.m. – 12:00 p.m.	IDSA comments regarding the Antiviral Medkits Proposal	Luciana Borio, M.D. Infectious Diseases Society of America (IDSA)
12:00 p.m. – 12:05 p.m.	American Medical Association perspective on use of Influenza antiviral “MedKit” during a pandemic influenza outbreak.	Litjen (L.J.) Tan, M.S., Ph.D. American Medical Association (AMA)
12:05 p.m. – 12:10 p.m.	American Academy of Pediatrics’ Perspective of Home Antiviral Drug Stockpiling	Henry (Hank) Bernstein, M.D. American Academy of Pediatrics (AAP)
12:10 p.m. – 12:15 p.m.	Distribution of Antivirals for Pandemic Influenza: Public Health Impact and Research Recommendations	Cynthia Reilly, B.S. Pharm. American Society of Health-System Pharmacists (ASHP)
12:15 p.m. – 12:20 p.m.	The American Pharmacists Association’s Comments on Stockpiling Pandemic Influenza Medkits	Marcie Bough, Pharm.D. American Pharmacists Association (APhA)
12:20 p.m. – 12: 25 p.m.	State Public Health Agency Perspective on Pan Flu Antivirals MedKits	James Blumenstock, M.D. Chief Program Officer, Public Health Practice The Association of State and Territorial Health Officials (ASTHO)
12:30 p.m. – 1:30 p.m.	Lunch	
1:30 p.m. – 2:30 p.m.	Open Public Hearing (OPH) Session	
2:30 p.m. – 2:45 p.m.	Charge to the Committee	Debra Birnkrant M.D. Director, Division of Antiviral Products CDER, FDA
2:45 p.m. – 5:00 p.m.	Advisory Committee Discussion	
5:00 p.m.	Adjourn	