June 7, 2007

Use of Medication Guides to Distribute Drug Risk Information to Patients; A Public Hearing; June 12 and 13, 2007

The Center for Drug Evaluation and Research (CDER) is announcing a public hearing to obtain feedback on the FDA requirement that patients receive information for certain drug and biological products that pose a serious and significant public health risk through the FDA-mandated Medication Guide Program. The following FDA representatives will participate on the expert panel: Paul Seligman, M.D., M.P.H., Associate Director, Safety Policy and Communication Staff, Ilisa Bernstein, PharmD., J.D., Director of Pharmacy Affairs, Office of the Commissioner, Gerald Dal Pan, M.D., M.H.S., Director, Office of Surveillance and Epidemiology, John Jenkins, M.D., Director, Office of New Drugs, Lisa Mathis, M.D., Associate Director, Pediatric and Maternal Health Staff, Robert Temple, M.D., Director, Office of Medical Policy, Jason J. Y. Woo, M.D., M.P.H., Associate Director, Scientific and Medical Affairs, Office of Compliance.

Agenda – June 12, 2007

8:30 a.m. – Welcome –Randall Lutter, Ph.D., Acting Deputy Commissioner for Policy

8:40 a.m. – Opening Remarks – Steven Galson, M.D., M.P.H., Director, Center for Drug Evaluation and Research

8:50 a.m. – Medication Guide Historical Perspective – Paul Seligman, M.D. M.P.H., Associate Director, Safety Policy and Communication, Center for Drug Evaluation and Research

Panel 1

9:10 a.m.	Honorable Mike Ferguson, House of Representatives
	Mrs. Lisa Van Syckel, Drugawareness
	Ms. Nicole Cumber, Consumer
	Ms. Laurie Yorke, Consumer
	Mr. Robert Manciero, Full Vision Productions

10:30 a.m. – Break

Panel 2

10:45 a.m.	Dr. Nancy Allen LaPointe, Duke Clinical Research Institute
	Mr. William Lang, American Association of Colleges of Pharmacy
	Dr. Ruth Day, Duke University
	Dr. Michael Wolf, Northwestern University

12:00 p.m. – Lunch

Panel 3

1:00 p.m. Ms. Kim Witczak, Consumer
Mrs. Vera Hassner Sharav, Alliance for Human Research Protection
Ms. Ellen Liversidge, Alliance for Human Research Protection
Ms. Diane Dorlester, Mental Health America
Dr. Anthony Ng, Mental Health America

2:30 p.m. - Break

Panel 4

2:45 p.m. Mr. Tom Lawlor, Walgreen Company
Mr. Thomas Flottman, Pharmaceutical Printed Literature Association
Dr. John Coster, National Association of Chain Drug Stores
Mr. Steve Heidenthal, CVS/CareMark
Ms. Cathy Russos/Mr. Ben Stone, Pharmex

4:30 p.m. – Closing remarks

June 13, 2007

8:30 a.m. – Opening Remarks- Paul Seligman, M.D.

Panel 5

8:45 a.m. Dr. Alex Michaels, Health Professional
Mr. Ray Bullman, National Council on Patient Information and Education
Ms. Rebecca Burkholder, National Consumers League
Dr. John Kamp, Coalition of Healthcare Communication
Ms. Marcie Bough, American Pharmacists Association

10:00 a.m. – Break

Panel 6

10:15 a.m. Dr. Catherine Melfi, Lilly
Dr. Isma Benattia, Wyeth
Dr. Jeffrey Stoddard, Covance
Mrs. Marissa Craddock, Roxane Laboratories for GPHA
Mr. Paul Johnson, Wolters Kluwer Health
Dr. Kala Paul, Corvallis Group

12:00 a.m. – Lunch

Panel 7

1:00 p.m. Dr. Gerald McEvoy, American Society of Health-Systems Pharmacists
Ms. Becky Snead, National Alliance of State Pharmacy Associations
Mr. Bryan Ziegler, National Community Pharmacists Association
Ms. Anita Ducca, Healthcare Distribution Management Association
Mrs. Danielle Daignault, Gold Standard, An Elsevier Company

2:15 p.m. – Break

Panel 8

2:30 p.m. Dr. David Fassler,
American Academy of Child and Adolescent Psychiatry
Dr. Darrel Regier, American Psychiatric Association
Dr. Carol Watkins, CHADD
Mrs. Janet Sisk, Juvenile Justice Foundation
Mrs. Susan Nelson, Consumer

4:00 p.m. – Closing Remarks – Paul Seligman, M.D.