Marketed Unapproved Drugs Workshop
January 9, 2007
8:30 AM - 4:30 PM
Universities at Shady Grove Conference Center
9640 Gudelsky Drive, Auditorium - Bldg. 1, Rockville, MD

8:30	Conference Introduction *Deborah M. Autor, Esq.* *Director, Office of Compliance*
8:30-8:45	Opening Remarks *Andrew C. von Eschenbach, M.D.* *Commissioner, Food & Drug Administration*
8:45-9:00	Welcome *Steven K. Galson, M.D., M.P.H.* *Director, Center for Drug Evaluation and Research*
9:00-9:15	Overview of the "Unapproved Universe" *Deborah M. Autor, Esq.* *Director, Office of Compliance*
9:15-9:35	Regulatory Pathway: OTC Monograph *Reynold Tan, Ph.D.* *Interdisciplinary Scientist, Division of Nonprescription Regulation Development, Office of Nonprescription Products*
9:35-10:00	Chemistry, Manufacturing, and Controls Requirements *Moheb M. Nasr, Ph.D.* *Director, Office of New Drug Quality Assessment*
	Break
10:15-10:45	Regulatory Pathway: ANDA *Gary Buehler* *Director, Office of Generic Drugs*
10:45-11:05	Regulatory Pathway: NDA Process *Kim Colangelo* *Associate Director for Regulatory Affairs, Office of New Drugs*
11:05-11:45	NDA/Demonstrating Product Effectiveness *Robert Temple, M.D., Director, Office of Medical Policy and Acting Director, Office of Drug Evaluation I*
11:45-12:30	Question & Answer Session

12:30-1:45 Lunch

1:45-2:15 NDA/Demonstrating Product Safety
(pre-clinical and clinical requirements)
John Jenkins, M.D.
Director, Office of New Drugs

David Jacobson-Kram, Ph.D., DABT
Associate Director for Pharmacology and Toxicology,
Office of New Drugs

Robert J. Meyer, M.D.
Director, Office of Drug Evaluation II

2:15-2:30 Pediatric Research Equity Act: Pediatric Considerations
Lisa Mathis, M.D.
Associate Director, Pediatrics and Maternal Health Staff,
Office of New Drugs

2:30-3:00 Patent and Non-Patent Exclusivities
Kim Dettelbach
Office of the General Counsel

3:00-3:15 User Fees & Waivers
Mike Jones
Special Assistant, Office of Regulatory Policy

3:15-3:25 Role of the Unapproved Drugs Coordinator
Sally Loewke, M.D.
Assistant Director for Guidance & Policy and
Unapproved Drugs Coordinator, Office of New Drugs

Break

3:45-4:30 Question and Answer Session

4:30 Closing