

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research (CDER)

*Joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee*

## AGENDA

October 18, 2007

Day 1

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*The committees will discuss the safety and efficacy of over-the-counter (OTC) cough and cold products marketed for pediatric use.*

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8:00	Call to Order Introduction of Committee	<b>Mary Tinetti, M.D.</b> Chair, Nonprescription Drugs Advisory Committee
		<b>Marsha D. Rappley, M.D.</b> Chair, Pediatric Advisory Committee
	Conflict of Interest Statement	<b>Darrell Lyons, BSN, RN</b> Designated Federal Official
8:30	OTC Cough and Cold Products: Use in Children	<b>Joel Schiffenbauer, M.D., Deputy Director</b> Office of Nonprescription Products CDER, FDA
8:40	Regulatory History of Pediatric Cough/Cold Products:	<b>Marina Y. Chang, R.Ph., Team Leader</b> Office of Nonprescription Products CDER, FDA
	<b>PETITIONER PRESENTATIONS</b>	
8:55	Cough and Cold Preparations for Young Children: Overview and Petition	<b>Joshua M. Sharfstein, M.D.</b> Commissioner of Health, Baltimore City
	Efficacy of Cough and Cold Preparations for Young Children	<b>Wayne R. Snodgrass, M.D., Ph.D.</b> Professor, University of Texas Medical Branch
	Safety of Cough and Cold Preparations in Young Children	<b>Michael Shannon, M.D., M.P.H.</b> Professor of Pediatrics, Harvard Medical School
	Cough and Cold Preparations in Young Children: Practical Considerations	<b>Daniel J. Levy, M.D.</b> President, MD Chapter, American Academy of Pediatrics
10:00	<b>Break</b>	
10:15	<b>INDUSTRY PRESENTATIONS</b>	
	Introduction	<b>Linda Suydam, D.P.A.</b> President CHPA
	Efficacy Research	<b>Phil Walson, M.D.</b> University of Cincinnati Pediatrician
	Pharmacokinetics	<b>Cathy Gelotte, Ph.D.</b> McNeil Consumer Healthcare

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(continued)

	Safety	<b>Richard Dart, M.D.,</b> Rocky Mountain Poison and Drug Center & <b>Ed Kuffner, M.D.</b> McNeil Consumer Healthcare
	Industry Commitments & Recommendations	<b>Linda Suydam, D.P.A.</b> President, CHPA
12:00	<b>Lunch</b>	
	<b>FDA PRESENTATIONS</b>	
1:15	Clinical Pharmacology Perspectives of Pediatric Dosing of OTC Cough & Cold Medicines	<b>Partha Roy, Ph.D., Senior Clinical Pharmacologist</b> Office of Clinical Pharmacology CDER, FDA
1:35	Considerations for Extrapolation of Efficacy from Adults to Children; Examples and Experience from the Division of Pulmonary & Allergy Products	<b>Peter Starke, M.D., Associate Director for Safety &amp; Charles E. Lee, M.D., Medical Team Leader</b> Division of Pulmonary & Allergy Products CDER, FDA
1:50	Literature Review: Safety and Efficacy of OTC Cough/Cold Drug Products in Pediatric Patients	<b>Lolita A. Lopez, M.D., Medical Officer</b> Office of Nonprescription Products CDER, FDA
2:05	Adverse Events and Poisonings Associated with Cough and Cold Products in Children Less Than 6 Years of Age	<b>Gita Akhavan-Toyserkani, Pharm.D., MBA, Safety Evaluator</b> Office of Surveillance and Epidemiology, CDER, FDA
2:30	Over-the-Counter Cough/Cold Products Medication Errors	<b>Richard Abate, R.Ph., MS, Safety Evaluator</b> Office of Surveillance and Epidemiology, CDER, FDA
2:45	<i>Questions for Speakers</i>	
3:15	<b>Break</b>	
3:45	<i>Questions for Speakers/Committee Discussion</i>	
5:00	<b>Adjourn</b>	

# FOOD AND DRUG ADMINISTRATION

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## AGENDA

October 19, 2007

Day 2

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*The committees will discuss the safety and efficacy of over-the-counter (OTC) cough and cold products marketed for pediatric use.*

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- 8:00 Call to Order  
Introduction of Committee Chair, NDAC
- Conflict of Interest Statement **Darrell Lyons, BSN, RN**  
Designated Federal Official
- 8:30 *Open Public Hearing*
- 10:30 **Break**
- 10:45 *Questions and Panel Discussion*
- 12:00 **Lunch**
- 1:15 *Questions and Panel Discussion*
- 4:00 **Adjourn**