

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

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

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

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October 18, 2007

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| | Safety | Richard Dart, M.D.,
Rocky Mountain Poison and Drug Center &
Ed Kuffner, M.D.
McNeil Consumer Healthcare |
| | Industry Commitments & Recommendations | Linda Suydam, D.P.A.
President, Consumer Healthcare Products Association |
| 12:00 | Lunch | |
| | FDA PRESENTATIONS | |
| 1:15 | Clinical Pharmacology Perspectives of Pediatric Dosing of OTC Cough & Cold Medicines | Partha Roy, Ph.D., Senior Clinical Pharmacologist
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 | Peter Starke, M.D., Associate Director for Safety & Charles E. Lee, M.D., Medical Team Leader
Division of Pulmonary & Allergy Products CDER, FDA |
| 1:50 | Literature Review: Safety and Efficacy of OTC Cough/Cold Drug Products in Pediatric Patients | Lolita A. Lopez, M.D., Medical Officer
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 | Gita Akhavan-Toyserkani, Pharm.D., MBA, Safety Evaluator
Office of Surveillance and Epidemiology, CDER, FDA |
| 2:30 | Over-the-Counter Cough/Cold Products Medication Errors | Richard Abate, R.Ph., M.S., Safety Evaluator
Office of Surveillance and Epidemiology, CDER, FDA |
| 2:45 | <i>Questions for Speakers</i> | |
| 3:15 | Break | |
| 3:45 | <i>Questions for Speakers/Committee Discussion</i> | |
| 5:00 | Adjourn | |

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October 19, 2007

Day 2

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 | Mary Tinetti, M.D.
Chair, Nonprescription Drugs Advisory Committee |
| | | Marsha D. Rappley, M.D.
Chair, Pediatric Advisory Committee (<i>via telephone</i>) |
| | Conflict of Interest Statement | Darrell Lyons, BSN, RN
Designated Federal Official |
| 8:30 | <i>Open Public Hearing</i> | |
| 10:30 | Break | |
| 10:45 | <i>Questions and Panel Discussion</i> | |
| 12:00 | Lunch | |
| 1:15 | <i>Questions and Panel Discussion</i> | |
| 4:00 | Adjourn | |