

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

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

Hilton Washington DC/Silver Spring, The Ballrooms
8727 Colesville Road, Silver Spring, MD

MAY 17 – 18, 2011

AGENDA

The committees will review pertinent pharmacokinetic (how drugs are absorbed, distributed, used, and eliminated by the body), safety and efficacy data, and discuss whether new dosing information for oral over-the-counter (OTC) drug products containing acetaminophen should be added to the label for children less than 2 years of age. In addition, the committees will consider adding a weight-based dosing regimen to the existing age-based dosing regimen for children 2 to 12 years of age. Dosing for children 12 years of age and older will not be discussed. Lastly, the committees will discuss ways that administration by caregivers can be improved so that medication errors can be minimized.

Day 1: May 17, 2011

8:00 a.m.	Call to Order and Opening Remarks	Richard Neill, M.D. Acting Chair Nonprescription Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Diem-Kieu H. Ngo, Pharm.D., BCPS Designated Federal Officer
8:15 a.m.	FDA Introductory Remarks	M. Scott Furness, Ph.D. Director Division of Nonprescription Regulation Development (DNRD) Office of Drug Evaluation IV (ODE-IV) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	FDA PRESENTATION	
	Regulatory History of Pediatric Acetaminophen Dosing	Kathleen M. Phelan, R.Ph. Interdisciplinary Scientist DNRD, ODE-IV, OND, CDER, FDA
	Clinical Pharmacology Findings of Acetaminophen in Pediatric Patients	Ping Ji, Ph.D. Senior Clinical Pharmacologist Division of Clinical Pharmacology II Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

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

Hilton Washington DC/Silver Spring, The Ballrooms
8727 Colesville Road, Silver Spring, MD

May 17 – 18, 2011

AGENDA

-continued-

FDA PRESENTATION (CONT.)

Literature Review: Efficacy and
Safety of Acetaminophen in
Children 6 months to 2 years of Age

Jane Filie, M.D.
Medical Officer
DNRD, ODE-IV, OND, CDER, FDA

Review of Extrapolation: What It Is
and Why We Use It

Lisa Mathis, M.D.
Associate Director
Pediatric and Maternal Health Staff
OND, CDER, FDA

9:50 a.m. Clarifying Questions

10:05 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATION (CONT.)**

Introduction to Office of Surveillance
and Epidemiology Presentations

Irene Z. Chan, Pharm.D., BCPS
Team Leader
Division of Medication Error Prevention and Analysis
(DMEPA)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

Single-Ingredient Acetaminophen
Utilization Patterns

Tracy Pham, Pharm.D.
Drug Use Analyst
Division of Epidemiology II (DEPI-II)
OSE, CDER, FDA

Acetaminophen-Exposure Associated
Problems in Children in the U.S.:
A Review of U.S. Poison Control
Center Calls Data for 2002-2008

Margie Goulding, Ph.D.
Epidemiologist
DEPI-II, OSE, CDER, FDA

10:50 a.m. Clarifying Questions

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

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

Hilton Washington DC/Silver Spring, The Ballrooms
8727 Colesville Road, Silver Spring, MD

May 17 – 18, 2011

AGENDA

-continued-

11:05 a.m. **FDA PRESENTATION (CONT.)**

Hospitalization Rates for
Acetaminophen-Associated
Poisonings in Children

Syed Rizwanuddin Ahmad, M.D., M.P.H.
Medical Epidemiologist
DEPI-II, OSE, CDER, FDA

Acetaminophen Overdose
Among Children

Maria E. Suarez-Almazor, M.D., Ph.D.
Barnts Family Distinguished Professor
University of Texas MD Anderson Cancer Center
Houston, Texas

11:25 a.m. Clarifying Questions

11:40 a.m. **FDA PRESENTATION (CONT.)**

Review of Acetaminophen
Postmarketing Adverse Event
Reports and Medical Literature

Peter Waldron, M.D.
Medical Officer
Division of Pharmacovigilance II, OSE, CDER, FDA

Medication Errors Associated with
Pediatric Use of Oral Acetaminophen

Irene Z. Chan, Pharm.D., BCPS
Team Leader, DMEPA, OSE, CDER, FDA

12:15 p.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:30 p.m. **INDUSTRY PRESENTATION**

Introductory Remarks

Barbara Kochanowski, Ph.D.
Vice President, Regulatory Affairs
Consumer Healthcare Products Association (CHPA)

Acetaminophen Pharmacokinetic
Data in Children

Cathy Gelotte, Ph.D.
Senior Director, Clinical Pharmacology
McNeil Consumer Healthcare

Acetaminophen Efficacy and Safety,
and Weight-Based Dosing

Ed Kuffner, M.D.
Vice President, Medical Affairs and Clinical Research,
McNeil Consumer Healthcare

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

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

Hilton Washington DC/Silver Spring, The Ballrooms
8727 Colesville Road, Silver Spring, MD

May 17 – 18, 2011

AGENDA

-continued-

INDUSTRY PRESENTATION (CONT.)

Safe Use of OTC Acetaminophen
in Children

Randall Bond, M.D.

Director

Cincinnati Children's Hospital Medical Center

Industry Initiatives,
Concluding Remarks

Barbara Kochanowski, Ph.D.

3:00 p.m. Clarifying Questions

3:15 p.m. **BREAK**

3:30 p.m. Open Public Hearing

5:30 p.m. Adjournment

Day 2: May 18, 2011

8:00 a.m. Call to Order and Opening Remarks

Richard Neill, M.D.

Acting Chair

Nonprescription Drugs Advisory Committee

Introduction of Committee

Conflict of Interest Statement

Diem-Kieu H. Ngo, Pharm.D., BCPS

Designated Federal Officer

8:15 a.m. FDA Introductory Remarks

M. Scott Furness, Ph.D.

Director, DNRD, ODE-IV, OND, CDER, FDA

8:20 a.m. Panel Discussions/Questions

10:00 a.m. **BREAK**

10:15 a.m. Panel Discussions/Questions

12:00 p.m. Adjournment