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

Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)

Advisors & Consultants Staff Conference Room, Rm 1066
5630 Fishers Lane, Rockville, MD 20857

JULY 22-23, 2008

AGENDA

Day 1: Tuesday, July 22, 2008

8:30 a.m.	Call to Order and Opening Remarks	**Ken R. Morris, Ph.D.** Chair Advisory Committee for Pharmaceutical Science and Clinical Pharmacology (ACPS-CP)
	Introduction of Committee	
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D., BCPS** Acting Designated Federal Official
8:45 a.m.	Welcome, Introductory Remarks, and OPS Update	**Helen Winkle** Director, Office of Pharmaceutical Science (OPS) Center for Drug Evaluation and Research (CDER), FDA
	Topic 1: Nanotechnology in Drug Manufacturing, Drug Delivery, and Drug Products	
	Topic Introduction	**Keith Webber, Ph.D.** Deputy Director, OPS, CDER, FDA
	CYT-6091 (Aurimune™): A Model Nanomedicine	**Lawrence Tamarkin, Ph.D.** President & CEO CytImmune Sciences, Inc.
10:15 a.m.	**BREAK**	
10:30 a.m.	Nanoparticle Technology: Leveraging Rapid Dissolution to Improve Performance of Poorly Water-soluble Drugs	**Stephen B. Ruddy, Ph.D.** Senior Director, Pharmaceutical Development Elan NanoSystems
	Nanotools for Toxicity Assessment of Nanomedicines	**Darin Y. Furgeson, Ph.D.** Assistant Professor of Pharmaceutical Sciences and Biomedical Engineering, Biomedical Engineering Center for Translational Research University of Wisconsin-Madison
	Committee discussions and recommendations	

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Day 1: Tuesday, July 22, 2008, continued

12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	***Topic 2: Lead in Pharmaceutical Products***	
	Historical Background and Introduction	**Norman Schmuff, Ph.D.** Branch Chief, Division of Pre-Marketing Assessment II, Office of New Drug Quality Assessment (ONDQA), OPS, CDER, FDA
	Effects of Lead Exposure in Adults, Children, and Special Populations	**Susan Cummins, M.D., M.Ph.** Senior Science Advisor Pediatric and Maternal Health Staff (PMHS) Office of New Drugs (OND), CDER, FDA
	FDA Drug Product Survey	**John Kaufman, Ph.D.** R&D Team Leader, Division of Pharmaceutical Analysis (DPA), Office of Testing and Research (OTR), OPS, CDER, FDA
3:15 p.m.	**BREAK**	
3:30 pm	USP Controls on Lead in Pharmaceutical Products	**Darrell Abernethy, M.D., Ph.D.** Chief Science Officer United States Pharmacopeia
	CFSAN's Approach to Setting Lead Limits	**Michael E. Kashtock, Ph.D.** Supervisory Consumer Safety Officer Division of Plant and Dairy Food Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition (CFSAN), FDA
	Topic Summary and Questions	**Norman Schmuff, Ph.D.**
	Committee discussions and recommendations	
5:00 p.m.	**ADJOURNMENT**	

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Day 2: Wednesday, July 23, 2008

8:30 a.m.	Call to Order	**Ken R. Morris, Ph.D.** Chair, ACPS-CP
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D., BCPS** Acting Designated Federal Official
8:45 a.m.	***Topic 1: Bioequivalence Methods for Locally Acting Drugs that Treat Gastrointestinal (GI) Conditions***	
	Bioequivalence of Locally Acting GI Drugs: An Overview	**Lawrence Yu, Ph.D.** Director for Science, Office of Generic Drugs (OGD), OPS, CDER, FDA
	Why is the *In Vitro* Method Better than the *In Vivo* Method?	**James Polli, Ph.D.** University of Maryland School of Pharmacy Department of Pharmaceutical Sciences
10:00 a.m.	**BREAK**	
10:15 a.m.	OGD Recommendations for Poorly Soluble Locally Acting GI Drugs	**Robert Lionberger, Ph.D.** Chemical Engineer OGD, OS, CDER, FDA
	Committee discussions and recommendations	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	***Topic 2: Drug Classification of Orally Disintegrating Tablets (ODT)***	
	Topic Introduction	**Frank Holcombe, Ph.D.** Associate Director for Chemistry OGD, OPS, CDER, FDA
	Committee discussions and recommendations	

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3:00 p.m. **BREAK**

3:15 p.m. ***Topic 3: Use of Inhaled Corticosteroid Dose Response as a Means to Establish Bioequivalence of Inhalation Drug Products***

Bioequivalence of Inhalation Drug Products: Challenges and Opportunities	**Lawrence Yu, Ph.D.**
Asthma Stability Model for Inhaled Corticosteroid Dose-response	**Wallace P. Adams, Ph.D.** Leading Pharmacologist, OGD Science Staff OGD, OPS, CDER, FDA
Exhaled Nitric Oxide Study Model for Inhaled Corticosteroid Dose-response	**Badrul A. Chowdhury, M.D., Ph.D.** Director, Division of Pulmonary and Allergy Drug Products (DPAP), Office of Drug Evaluation II (ODE II), OND, CDER, FDA

4:45 p.m. **Conclusion and Summary Remarks** **Helen Winkle**

5:00 p.m. **ADJOURNMENT**