Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee

August 4, 2005

CDER Advisory Committee Conference Room
5630 Fishers Lane, Rockville, Maryland

AGENDA

The Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee will discuss new drug application (NDA) 21-645, proposed trade name MT100 (naproxen sodium and metoclopramide hydrochloride) Tablets, Pozen, Inc., for the proposed indication of acute treatment of migraine headache with or without aura.

8:00	Call to Order and Opening Remarks	Karl Kieburtz, M.D., M.P.H. Acting Chair, PCNS
		Anuja Patel, M.P.H. Executive Secretary, CDER, FDA
	Conflict of Interest Statement	Mary Ann Killian Program Integrity Advisor Ethics and Integrity Staff Office of Management Programs Office of Management, FDA
	Introduction of Committee Financial Disclosure Statements	
8:15	Overview of Issues	Russell Katz, M.D. Director, Division of Neurology Products (DNP), FDA
8:30	<u>Sponsor Presentations</u> Pozen Incorporated	
	• Introduction and Summary	Marshall E. Reese, Ph.D. Executive Vice President, Product Development Pozen Incorporated
	• Overview of Tardive Dyskinesia	A.H.V. (Tony) Schapira, M.D. Professor of Neurology, Royal Free Hospital School of Medicine London, United Kingdom
	• Review of MT100 Efficacy	William James Alexander, M.D., M.P.H., F.A.C.P Senior Vice President, Clinical Development Chief Medical Officer Pozen Incorporated
	• Potential Role of MT100 in Migraine Therapy: Balancing Benefits and Risks	David B. Matchar, M.D., F.A.C.P. Director, Duke Center for Clinical Health Policy Research Professor of Medicine Duke University School of Medicine
	• Clinical Considerations on Migraine Treatment	Stephen D. Silberstein, M.D. Director, Jefferson Headache Center Thomas Jefferson University Hospital

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AGENDA (cont.)

9:45	Break	
10:00	FDA Presentations	
	• FDA Risk/Benefit Considerations	Eric Bastings, M.D. Clinical Team Leader, DNP, FDA
	• Overview of Tardive Dyskinesia	Hyder A. Jinnah, M.D., Ph.D. The Johns Hopkins Hospital
	• Post-marketing Review of Movement Disorders and Neuroleptic Malignant Syndrome Associated with Metoclopramide	Mary Ross Southworth, Pharm.D. Safety Evaluator, Division of Drug Risk Evaluation, Office of Drug Safety, FDA
11:15	Questions from the Committee to the Sponsor and FDA	
Noon	**Lunch**	
1:00	Open Public Hearing	
2:00	Committee Discussion and Response to FDA Questions	
5: 00	**Adjourn**	