FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND
DECEMBER 13, 2007

AGENDA

The committee will evaluate data submitted by Merck & Co., Inc. to support the over-the-counter use of Mevacor (lovastatin) 20 milligrams a day to help lower cholesterol which may prevent a first heart attack.

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	**Mary E. Tinetti, M.D.** Chair, Nonprescription Drugs Advisory Committee
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D.** Designated Federal Official
8:15 a.m.	FDA Introductory Remarks	**Andrea Leonard-Segal, M.D.,** Director, Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products, CDER, FDA
	APPLICANT PRESENTATION	
8:30 a.m.	Introduction	**Edwin Hemwall, Ph.D.** Executive Director Worldwide OTC Regulatory & Scientific Affairs Merck Research Laboratories
8:35 a.m.	Public Health Opportunity	**Valentine Burroughs, M.D., M.B.A.** Associate Professor of Medicine Mount Sinai Medical School, NYC
8:45 a.m.	Lovastatin: Safety and Efficacy	**Ingrid Adamsons, M.D., M.P.H.** Senior Director, Clinical Research Merck Research Laboratories
9:00 a.m.	CUSTOM Study Overview	**Jerry Hansen, R.Ph., M.B.A.** Executive Director, Consumer Behavior Research Rx-to-OTC Switch Merck Research Laboratories
9:10 a.m.	SELECT Study Results	**Edwin Hemwall, Ph.D.** Executive Director Worldwide OTC Regulatory & Scientific Affairs Merck Research Laboratories
9:35 a.m.	Education, Support, and Monitoring	**Saul Shiffman, Ph.D.** Professor of Psychology, Psychiatry & Pharmaceutical Sciences, University of Pittsburgh

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee

HILTON WASHINGTON, DC/SILVER SPRING
8727 COLESVILLE ROAD, SILVER SPRING, MARYLAND
DECEMBER 13, 2007

AGENDA
-CONTINUED-

9:45 a.m.	Marketing Plans	**George Quesnelle** President Consumer Healthcare – North America GlaxoSmithKline Consumer Healthcare
9:55 a.m.	Conclusion	**Edwin Hemwall, Ph.D.** Executive Director Worldwide OTC Regulatory & Scientific Affairs Merck Research Laboratories

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

FDA PRESENTATION

10:15 a.m. History of the Label and Label Comprehension Studies

LDL-C vs. TC Labeling Paradigm

Self Selection Studies Past and Present

Hepatic Safety Study

Statins and ALS

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

1:30 p.m. Open Public Hearing

2:30 p.m. Questions/Discussion

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

3:30 p.m. Questions/Discussion

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