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	**Mary E. Tinetti, M.D.** Chair, Nonprescription Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	**Diem-Kieu H. Ngo, Pharm.D.** Designated Federal Official
8:10 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

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-

9:35 a.m.	Education, Support, and Monitoring	**Saul Shiffman, Ph.D.** Professor of Psychology, Psychiatry & Pharmaceutical Sciences, University of Pittsburgh
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.	LDL-C vs. TC Labeling Paradigm	**Eileen, Craig, M.D.** Medical Officer Division of Metabolism and Endocrinology Products
10:30 a.m.	History of the Label and Label Comprehension Studies	**CAPT Laura E. Shay, R.N., M.S., C-ANP** Social Science Analyst Division of Nonprescription Clinical Evaluation
10:50 a.m.	Self-Selection Study	**Linda Hu, M.D.** Medical Officer Division of Nonprescription Clinical Evaluation
11:25 a.m.	Hepatic Safety Study	**Shewit Bezabeh, M.D., M.P.H.** Medical Epidemiologist Division of Drug Risk Evaluation
11:45 a.m.	Statins and a Data Mining Signal for ALS	**Eric Colman, M.D.** Deputy Director, Lipid Team Leader Division of Metabolism and Endocrinology Products
12:10 p.m.	Questions/Clarifications	

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-

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**