FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

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

Holiday Inn - Versailles Ballrooms
Bethesda, Maryland
January 13, 2004

AGENDA
DAY 1

The committees will consider the safety and efficacy of new drug application (NDA) 21-213 proposing over-the-counter (OTC) use of Mevacor 20 mg a day, (lovastatin), Merck & Co., Inc., to help lower LDL "bad" cholesterol.

8:00	Call to Order and Introductions	**Alastair Wood, M.D., Chair (NDAC)**
	Conflict of Interest Statement	**LCDR Hilda Scharen, M.S.** Executive Secretary Nonprescription Drugs Advisory Committee
8:15	Welcome and Comments	**Charles Ganley, M.D., Director** Division of Over-the-Counter Drug Products Office of Drug Evaluation V
		David Orloff, M.D., Director Division of Metabolic and Endocrinologic Drug Products Office of Drug Evaluation II

8:30	Introduction Regulatory History and Overview of Current Proposed OTC Program	**Mary Parks, M.D., Deputy Director** Division of Metabolic and Endocrinologic Drug Products Office of Drug Evaluation II

Sponsor Presentation

9:00		**Edwin Hemwall, Ph.D., Vice President** Worldwide Regulatory and Scientific Affairs Johnson & Johnson / Merck Consumer Pharmaceuticals
9:30	Rationale for OTC Lovastatin	**Richard Pasternak, M.D. – VP, Clinical Research** Merck Research Labs
10:00	Mevacor OTC Self Management System	**Jerry Hansen, RPh - Vice President Business Development and Consumer Research** Johnson & Johnson / Merck Consumer Pharmaceuticals
10:30	**Break**	

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DRAFT AGENDA
DAY 1 (Continued)

Sponsor Presentation (Continued)

10:45	Actual Use Study Results	**Robert Tipping, M.S.** Director, Biostatistics Merck Research Labs
11:15	Medical Perspective and Conclusion	**Jerome D. Cohen, M.D., FACC, FACP** Professor of Internal Medicine/Cardiology Director, Preventive Cardiology Programs St. Louis University Health Sciences Center
11:45	**Questions from the Committee**	
12:15	**Lunch**	

FDA Presentation

1:15	Reproductive and Fetal Toxicity	**Karen Davis-Bruno, Ph.D.** Division of Metabolic and Endocrinologic Drug Products Office of Drug Evaluation II
1:45	Label Comprehension Study	**Laura Shay, RN, M.S., C-ANP** Division of Over-the-Counter (OTC) Drug Products Office of Drug Evaluation V
2:15	CUSTOM – Actual Use Study	**Daiva Shetty, M.D.** Division of Over-the-Counter (OTC) Drug Products Office of Drug Evaluation V
2:45	**Break**	
3:00	Nonprescription Simvastatin in the United Kingdom	**Michael Koenig, Ph.D.** Division of Over-the-Counter (OTC) Drug Products Office of Drug Evaluation V
3:30	**Questions from the Committee**	

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DRAFT AGENDA
DAY 2

The committees will consider the safety and efficacy of new drug application (NDA) 21-213 proposing over-the-counter (OTC) use of Mevacor 20 mg a day, (lovastatin), Merck & Co., Inc., to help lower LDL "bad" cholesterol.

8:00	Call to Order and Introductions	**Alastair Wood, M.D., Chair (NDAC)** **LCDR Hilda Scharen, M.S.** Executive Secretary Nonprescription Drugs Advisory Committee
8:15	**Open Public Hearing**	
9:30	**Questions from the Committee and Committee Discussion**	
12:00	Lunch	
1:00	**Questions to the Committee/Summary**	
3:00	**Adjournment**	