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December 9, 2004

David Orloff, M.D., Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II

c/o Central Document Control Room
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

Dear Dr. Orloff:

NDA 21-213: MEVACOR™ DAILY Tablets
(Nonprescription lovastatin 20 mg)

ADVISORY COMMITTEE BACKGROUND PACKAGE AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION

Reference is made to the New Drug Application (NDA) cited above submitted as an electronic archive on December 10, 1999, by Merck Research Laboratories (MRL), a Division of Merck & Co., Inc., and Johnson & Johnson ◦ Merck Consumer Pharmaceuticals Co. (JJMCPC). Additional reference is made to the October 6, 2000, Not-Approvable Action Letter, and to the August 24, 2004, complete response to the aforementioned action letter. Reference is also made to the correspondence from Ms. Hilda F. Scharen, Nonprescription Drugs Advisory Committee Executive Secretary, received via facsimile on November 10, 2004. That correspondence identified that the NDA cited above would be discussed at the Nonprescription Drugs Advisory Committee Meeting on January 13 and 14, 2005. Additional reference is made to a December 1, 2004, email from Ms. Cathy A. Groupe, R.N., B.S.N., requesting that the background package copies be sent to her in Ms. Scharen's absence. The original application provided for a 10 mg nonprescription (over-the-counter, OTC) form of lovastatin for the treatment of elevated cholesterol for primary prevention of coronary heart disease. This amendment supports use of nonprescription lovastatin 20 mg (as an adjunct to diet and exercise) in otherwise healthy individuals who have mild to moderately elevated low density lipoprotein cholesterol (130 -170 mg/dL), and multiple (2+) risk factors for coronary heart disease (CHD).

In accordance with the Federal Advisory Committee Act (ACA) and FDA's regulations governing disclosure of information concerning New Drug Applications in 21 CFR 314.430, Merck Research Laboratories is submitting a copy of the Advisory Background Package available for public disclosure without redaction for distribution to the Advisory Committee and FDA staff members in preparation for the Nonprescription Drugs Advisory Committee Meeting scheduled for January 13 and 14, 2005.

In response to her request, we are providing separately to Ms. Groupe forty paper copies and two electronic copies of the background package.

This Advisory Committee Background Package consists of materials available for public disclosure without redaction.

This supplemental application is formatted as required in Title 21 paragraph 314.50 of the Code of Federal Regulations and is being submitted in accordance with the January 1999, *Guidance for Industry – Providing Regulatory Submissions in Electronic Format – NDAs.* As an attachment to this letter, Merck

Research Laboratories (MRL), a Division of Merck & Co., Inc., is providing one Compact Disk (CD) which contains the submission. All documents requiring signatures for certification are included as paper for archival purposes.

All of the information is contained on one CD and is not more than 500 MB. We have taken precautions to ensure that the contents of this CD are free of computer viruses (Norton Anti-Virus 7.51, Symantec Corp., 2000) and we authorize the use of anti-virus software, as appropriate.

A list of reviewers from the Division of Metabolic and Endocrine Drug Products who should be provided access to this electronic submission on their desktops may be obtained from Ms. Margaret Simoneau, R.Ph., M.S., Senior Regulatory Project Manager, Division of Metabolic and Endocrine Drug Products.

We consider the information included in this submission to be a confidential matter, and request that the Food and Drug Administration not make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

If you have any questions, please contact Florence F. Vickers, Ph.D., F.C.P. (484-344-4511) or, in her absence, Edwin L. Hemwall, Ph.D. (484-344-2306).

Sincerely,

Florence F. Vickers, Ph.D., F.C.P.
Director
Worldwide OTC Regulatory Affairs
Merck Research Laboratories

Enclosure: CD

Hand Deliver

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