



NDA 19-643/S-079

Merck & Co., Inc.  
Attention: Kenneth A. Kramer  
Associate Director, Regulatory Affairs  
P.O. Box 1000, UG2CD-48  
North Wales, PA 19454-1099

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated August 8, 2007, received August 8, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mevacor (lovastatin) Tablets.

We acknowledge receipt of your submission dated October 22, 2007.

This supplemental new drug application provides for a new source for the active pharmaceutical ingredient (API) and a new manufacturing site for the drug product. Revisions to the manufacturing process, testing methods, and tablet embossing were also proposed. This supplement includes labeling changes to the **HOW SUPPLIED** section of the Mevacor package insert.

In the **HOW SUPPLIED** section, the “Mevacor” embossment on the 20 mg and 40 mg tablets has been eliminated. Additionally, the manufacture information has been revised to state that Mevacor tablets are manufactured for Merck by Genpharm Inc.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert) submitted August 8, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “**SPL for approved NDA 19-643/S-079.**”

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see [www.fda.gov/cder/ddmac](http://www.fda.gov/cder/ddmac).

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
HFD-001, Suite 5100  
5515 Security Lane  
Rockville, MD 20852

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Margaret Simoneau, M.S., R.Ph., Regulatory Project Manager, at (301) 796-1295.

Sincerely,

*{See appended electronic signature page}*

Mary Parks, M.D.  
Director  
Division of Metabolism and Endocrinology  
Products (DMEP)  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Eric Colman  
12/7/2007 09:56:32 AM  
Eric Colman for Mary Parks