

ELECTRONIC SUBMISSION INFORMATION

This NDA is being submitted in the following formats:

<u>FORMAT</u>	<u>INFORMATION INCLUDED</u>	<u>MEDIA FORMAT</u>	<u>DATE OF SUBMISSION</u>
Paper	(all information except CRTs and CRFs)	Paper	April 28, 1998
Electronic Archival Files	NDA Table of Contents, Case Report Tabulations, Case Report Forms	CD	April 28, 1998
Electronic Submission	(all information)	CD	May 13, 1998 (to [REDACTED])

We are submitting this application in accordance with the Guidance for Industry - Archiving Submissions in Electronic Format - NDAs, published September, 1997.

As noted in the Guidance document, this letter is being included as *cover.pdf* and includes:

- Appropriate regulatory information
- A description of the submission
- A description of which portions of the submission are presented only in paper, only in electronic format, or both paper and electronic format (*see above*)
- A description of the electronic submission including the contents of the media, their number and format, a description of the file types and the total size of the submission  
*The electronic archival files for Case Report Tabulations and Case Report Forms are provided on 1 CD. The files are provided in .PDF and .PDF catalogue index format. The total file size is approximately 330 MB.*
- Verification that the submission is virus free with a description of the software used to check the files for viruses  
*Merck Research Laboratories (MRL) has employed Norton anti-virus (NAV) software and has scanned all files. No viruses were detected.*
- A description of any deviation from the specifications in the guidance document  
*Reference is made to a telephone conversation held between Dr. Charles Hyman, MRL, and Mr. Ken Edmunds and Mr. David Isom, FDA, on January 15, 1998. During this conversation, the Agency agreed to MRL's proposal that the archival submission of the Case Report Forms (CRFs) will be in compliance with the new guidance document (Guidance for Industry - Archiving Submissions in Electronic Format - NDAs, published September, 1997) with the following exception: MRL will bookmark to the patient allocation number level but not to the visit and/or domain of each set of CRFs. However, in order to minimize reviewers' inconvenience in locating data, the PDF files are text based, as opposed to scanned images, thereby permitting detailed searches of the CRFs.*

Solomon Sobel, M.D., Director  
NDA 19-643 Tablets MEVACOR™ (Lovastatin)  
April 28, 1998

Page 4

MRL will work with the FDA to arrange orientation to the electronic submission for all interested Agency reviewers.

This application is formatted as required in Title 21, paragraph 314.50 of the Code of Federal Regulations. It consists of a complete "archival" copy (Blue Binders), comprising ten volumes and two "review" copies as described in the Statement of Organization which is attached to this letter.

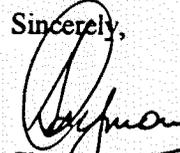
In accordance with the Food and Drug Administration Modernization Act of 1997, a check for this Supplemental New Drug Application in the amount of [REDACTED] (Check No. [REDACTED] User Fee I.D. No. [REDACTED] was sent to the Mellon Bank, Three Mellon Bank Center, 27th Floor (FDA [REDACTED] Pittsburgh, PA 15259-0001 [REDACTED]).

As required by Section 306(k)(1) of the Generic Enforcement Act [21 U.S.C. 335a(k)(1)], we hereby certify that, in connection with this application, Merck & Co., Inc. did not and will not use in any capacity the services of any person debarred under subsections 306(a) or (b) of the Act.

We consider the filing of this New Drug Application to be a confidential matter and request that the Food and Drug Administration not make its existence public without first obtaining written permission from Merck & Co., Inc.

Questions concerning this information should be directed to Charles L. Hyman, M.D. (610/397-2850) or, in my absence, Robert E. Silverman, M.D., Ph.D. (610/397-2944).

Sincerely,



Charles L. Hyman, M.D.  
Director, Regulatory Affairs

Attachment  
Federal Express #1

Desk Copy (Letter and Patent Information Only):

Mr. George Scott, HFD-984  
5516 Nicholson Lane, Rm. 238  
Rockville, MD 20857  
Federal Express #2

clh/fah  
q:\hark\mev\fd010L.doc

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
CSO INITIALS	DATE

NDA# 19-643/S-055

Mevacor (lovastatin) tablets

Merck Research Labs

Efficacy supplement based on results of AFCAPS/TexCAPS

Medical team leader note to the action package

Date: March 1, 1999

1. No safety update was required as all patients had completed the study at the time of the original submission.
2. The integrated summaries of safety and efficacy were included in the Medical Officer's review
3. Biopharmaceutics review not needed.

David G. Orloff, M.D.  
Medical Team Leader  
DMEDP/CDER/FDA

/s/

3-1-99

APPEARS THIS WAY ON ORIGINAL