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APPLICATION NUMBER: 19-766/S052

CORRESPONDENCE

## Document Information Page

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Letter Code: SNDA-11

COMIS Decision: AP: APPROVAL

Drafted by: Mas/March 9, 2002  
Revised by:  
Initialed by: M. Parks 3.14.02/E. Galliers 3.19.02  
Finalized: Mas 3.20.02  
Filename:

DFS Key Words:

Notes:

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## TELECOPIER MESSAGE

MERCK RESEARCH LABORATORIES  
REGULATORY AFFAIRS - DOMESTIC  
FIVE SENTRY PARKWAY EAST, BLUE BELL, PA 19422

TO: Margaret Simoneau, R.Ph. PHONE: (301) 827-6411

LOCATION: HFD-510, Room 14B-04 FAX: (301) 443-9282

FROM: Michael C. Elia, PhD, DABT PHONE: (484) 344-3180  
(formerly 610-397-3180)

LOCATION: BL A-20 FAX: (484) 344-2516  
(formerly 610-397-2516)

DATE: 9/19/2001 PAGES including cover sheet: 2 Pages

Special Comments: ZOCOR (situation)

Margaret: Attached is Merck's counterproposal for S-052. We've ask to go back to our proposed language, with the exception of deleting reference to \_\_\_\_\_

Only difference with FDA language is how risk factors are described, i.e., \_\_\_\_\_ vs lowered risk of high levels of HDL, Apo A1. Thanks,

Michael C. Elia, PhD, DABT  
Director, Regulatory Affairs *Mike*

Q/antell/elia/letters/FDA91901.doc

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Labeling

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/s/  
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David Orloff  
5/10/02 05:27:29 PM

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Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Drug Evaluation II

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**FACSIMILE TRANSMITTAL SHEET**

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**DATE: August 16, 2001**

<b>To:</b> Michael Elia, Ph.D., DABT	<b>From:</b> Margaret Simoneau
<b>Company:</b> Merck & Co., Inc.	Division of Division of Metabolic and Endocrine Drug Products
<b>Fax number:</b> 484-344-2516	<b>Fax number:</b> (301) 443-9282
<b>Phone number:</b> 484-344-3180	<b>Phone number:</b> (301) 827-6411
<b>Subject:</b> NDA 19-766/S-052 Labeling Comments	

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**Total no. of pages including cover:** 3

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**Comments:**

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**Document to be mailed:**       YES       NO

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NDA 19-766/S-052  
Zocor (Simvastatin) tablets  
Merck & Co., Inc.  
Submission date: November 30, 2000

Labeling comments to be incorporated under the CLINICAL PHARMACOLOGY section of the Zocor package insert:

"Epidemiological studies have established that elevated plasma levels of total-C, LDL-C and Apo B promote human atherosclerosis and are risk factors for developing CVD.

[ ]

Cleared for faxing by:

*(See appended electronic signature page)*

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Mary Parks, M.D.  
Medical Team Leader

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/s/

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Mary Parks

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