



JUN 20 1997

TRANSMITTED VIA FACSIMILE

Robert A. Brezin, R.Ph.
Director
US Regulatory Operations
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080

RE: NDA 20-261
Lescol (fluvastatin sodium)
MACMIS ID #5512

Dear Mr. Brezin:

Reference is made to Novartis Pharmaceuticals Corporations' (Novartis) April 15, 1997, Form FDA 2253 submission of a brochure entitled "Lescol Patients...You'll Know Them By Their Numbers" (LES1041) for Lescol.

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this brochure and finds it in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically, this brochure lacks fair balance because it fails to provide the WARNING related to myopathy and rhabdomyolysis that may occur with Lescol.

In order to address this objection, DDMAC recommends that Novartis take the following actions:

1. Immediately discontinue the above named brochure, and any other promotional materials for Lescol that fail to contain this important warning information.
2. Provide to DDMAC, in writing, Novartis's intent to comply with number one above.

Novartis's response should be received by June 30, 1997. If Novartis has any questions or comments, please contact Anne Reb by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

Mr. Robert Brezin
Novartis Pharmaceuticals Corporation
NDA 20-261

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In all correspondence related to this matter, please refer to
MACMIS ID #5512, in addition to the NDA number.

Sincerely,

A handwritten signature in cursive script that reads "Leah Palmer".

Leah Palmer, Pharm.D.
Branch Chief
Division of Drug Marketing,
Advertising and Communications