



Food and Drug Administration  
Rockville MD 20857

MAR 18 1998

**TRANSMITTED VIA FACSIMILE**

Mr. Salvatore P. Peritore  
Associate Director, Regulatory Affairs  
Lederle Laboratories  
401 North Middletown Road  
Pearl River, NY 10965-1299

**RE: ANDA #74-641**  
Selegiline, USP Tablets  
MACMIS# 6376

Dear Mr. Peritore:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for selegiline USP Tablets that are false, misleading, and in violation of the Federal Food, Drug, and Cosmetic Act. DDMAC refers to the journal ad "Getting doctors to switch could be easier than it appears" (ID #10484-00).

Specifically, this journal ad is misleading because it falsely implies that selegiline tablets are bioequivalent to Eldepryl capsules and interchangeable with them. Promotional materials must clearly indicate that bioequivalence, and therapeutic equivalence, of selegiline tablets is to the formerly marketed Eldepryl tablets.

DDMAC requests that Lederle Laboratories (Lederle) immediately suspend any further dissemination of this advertisement and all materials with similar violative messages. Lederle should respond, in writing, with its intent to comply with DDMAC's request by April 1, 1998. Lederle's response should include a list of all materials with this and similarly violative messages, and a description of the methods for discontinuing their use.

If Lederle has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

Mr. Salvatore Peritore  
Lederle Laboratories  
ANDA 74-641 (MACMIS 6376)

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In all future correspondence regarding this particular matter, please refer to MACMIS ID # 6376 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications