



APR - 6 2000

**TRANSMITTED VIA FACSIMILE**

Albert P. Mayo  
Director, Regulatory Affairs  
Organon  
375 Mount Pleasant Avenue  
West Orange, NJ 07052

**RE: NDA #20-415**  
Remeron (mirtazapine) Tablets  
MACMIS #8496

Dear Mr. Mayo:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a journal advertisement for Remeron that is lacking in fair balance and in violation of the Federal Food, Drug, and Cosmetic Act. Specifically, the currently running journal advertisement entitled "Life Without Depression..." (ID #ORG-46829) contains no risk information.

In addition, DDMAC notes that this journal advertisement was not submitted for review at the time of initial publication in compliance with 21 CFR §314.81.

To address this objection, DDMAC recommends that Organon do the following:

1. Immediately discontinue the use of this journal advertisement and any other promotional materials with the same or similar issues.
2. Provide DDMAC with a written response within 10 days of the date on this letter. Your response should include a statement of your intent to comply with the above and a list of all violative advertisements, including all of the journals that carry the advertisements.

If you have 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-42, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to  
MACMIS ID # 8496 in addition to the NDA number.

Sincerely,

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