



FOI

Food and Drug Administration  
Rockville MD 20857

MAY 14 1999

**TRANSMITTED VIA FACSIMILE**

Deborah S. Olon  
Manager, Research Administration  
Lotus Biochemical Corporation  
7335 Lee Highway  
P.O. Box 3586  
Radford, VA 24143-3586

**RE: ANDA# 87-639**  
Ergomar Sublingual Tablets (ergotamine tartrate tablets, USP)  
MACMIS # 7944

Dear Ms. Olon:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed promotional materials for Ergomar Sublingual Tablets (ergotamine tartrate tablets, USP) that are lacking fair balance, and thus is in violation of the Federal Food, Drug and Cosmetic Act. These materials include a journal ad (#120-RA029-6-0068-1), a flyer (#120-RA029-6-0071-1), and a press release (#120-RA028-6-0068-1).

Specifically, the journal ad is lacking fair balance because the risk information is presented in micro-sized font in the middle of a busy second page. Similarly, the directive to seek full prescribing information about Ergomar is presented in tiny type font. Thus, this promotional piece is lacking in fair balance because the risk information is not presented with a prominence and readability that is reasonably comparable to the presentation of information relating to the effectiveness of the drug.

The flyer and the press release are lacking fair balance because there is no risk information presented.

To address this issue, DDMAC requests that these materials be immediately discontinued along with any other materials with the same or similar violations. You should respond, in writing, to this request within 10 business days of the date of this letter. Your response should include your intent to comply with DDMAC's request and the materials that will be discontinued as a result of this letter.

Deborah S. Olson  
Lotus  
ANDA 87-693 (MACMIS 7944)

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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-40, 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 #7944 in addition to the NDA number.

Sincerely,

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