DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 22 1998

TRANSMITTED VIA FACSIMILE

Robert W. Ashworth
Director, Regulatory Affairs
Knoll Pharmaceutical Company
3000 Continental Drive-North
Mount Olive, New Jersey 07828-1234

Re: **NDA 20-632**
Meridia (sibutramine hydrochloride monohydrate) Capsules
MACMIS ID #7204

Dear Dr. Ashworth:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Meridia (sibutramine hydrochloride monohydrate) Capsules that are in violation of the Federal Food, Drug and Cosmetic Act (Act) and the regulations promulgated thereunder. Specifically, DDMAC objects to a direct-to-consumer 60-second television advertisement (ZFBB08096), included in an October 20, 1998, FDA form 2253 submission. A description of the objections is provided below.

Lacking in Fair Balance

The television advertisement is lacking in fair balance because the advertisement fails to present information relating to side effects and contraindications with a prominence reasonably comparable with the presentation of information relating to effectiveness of the drug. The risk information is presented in the audio portion of the advertisement against a visual background of busy activity and five scene changes. These visuals interfere with the audience's ability to comprehend and process the audio presentation disclosing Meridia's most important risks. In addition, the audio communication of the risk information is inadequate because it is not presented with a prominence, speed, or audibility reasonably comparable with the presentation of the product's benefits.

Furthermore, the statement, "It's a controlled substance so some patients may experience limited dependence" is misleading because it does not adequately convey to consumers the potential risks associated with the use of Meridia as related to its designation as a controlled substance.

Indication Statement

The advertisement is misleading because it does not adequately communicate Meridia's indication from its approved product labeling. The audio presentation of the statement, "If you're significantly overweight," combined with the "super" (visual only) presentation of the statement, "At least 25-45 lbs. overweight, depending on height" does not adequately convey the limitations to the population of patients indicated for treatment with Meridia. Specifically, the "super" does not present the indicated patient population description in a sufficiently prominent manner to enable the audience to comprehend and process this integral piece of Meridia's indication.

Knoll should immediately discontinue the use of the broadcast advertisement and other promotional materials that contain the same or similar representations for Meridia discussed above. Knoll should submit a written response to DDMAC on or before November 2, 1998, confirming that Knoll has discontinued the use of such materials.

If Knoll has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #7204 in addition to the NDA number. DDMAC reminds Knoll that only written communications are considered official.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications