DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 16 1997

TRANSMITTED VIA FACSIMILE

Keith Rotenberg
Director of Regulatory Affairs
Forest Laboratories, Inc.
909 3rd Avenue
23rd Floor
New York, New York 10022

RE: Levothroid (levothyroxine Sodium Tablets USP)
MACMIS ID # 5783

Dear Mr. Rotenberg:

Reference is made to Forest Laboratories, Inc.'s (Forest) advertisement for Levothroid titled "A Substitute Is In" (I-96-91). The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this advertisement and finds it to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

Specifically, DDMAC objects to the following claims and representations:

> The headline "A Substitute Is In." and statement "Levothroid can be used in place of Synthroid and Levoxyl in 47 states" are misleading because they suggest that Levothroid is a new product that has been determined to be bioequivalent to Synthroid and Levoxyl by an official body such as the Food and Drug Administration. However, levothyroxine products are not currently recognized by the FDA as bioequivalent.

Therefore, DDMAC requests that Forest immediately discontinue this advertisement and all other promotional materials with similar issues. DDMAC requests that Forest submit a written response by October 31, 1997, indicating your intent to comply with this recommendation. Forest's response should include a list of all materials that have been discontinued.

If Forest has any questions or comments, please contact me 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.

In all future correspondence regarding the materials discussed in this letter, please refer to MACMIS ID #5783 in addition to the product name.

Sincerely,

Anne M. Reb, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications