



TRANSMITTED VIA FACSIMILE

Amy Rubin
Director of Regulatory Affairs
Forest Laboratories, Incorporated
Harborside Financial Center
Plaza Threeé, Suite 602
Jersey City, NJ 07311

DEC 27 2000

RE: Levothroid (levothyroxine sodium tablets, USP)
MACMIS ID# 9499

Dear Ms. Rubin:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of an advertisement for Levothroid entitled "Smile" (55-110513) that was published in the December, 2000, issue of U.S. Pharmacist magazine. The advertisement lacks fair balance and contains false or misleading claims, in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations.

Lack of Fair Balance

The advertisement includes claims for Levothroid (for example, "provides precise hypothyroidism control") but fails to provide any information regarding side effects and contraindications (including warnings and precautions). Therefore, the advertisement lacks fair balance.

False or Misleading Claims

The claim "Levothroid offers you the lowest Average Wholesale Price of the three leading levothyroxines" is misleading because it lacks the context that the bioequivalence of these products has not been established.

The claim "Levothroid has the widest range of LT4 dosing options available" is misleading because it implies that there are no other levothyroxine products with the same number of dosing options. There is, however, at least one other currently marketed levothyroxine sodium product also available in 12 strengths.

Conclusion and Recommendation

Forest should immediately cease dissemination of this violative advertisement and all other promotional materials with the same or similar claims. Forest should respond to this letter on or before January 11, 2001. Your response should include a list of all similarly violative promotional materials and your method for discontinuing their use. It should be directed to me 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.

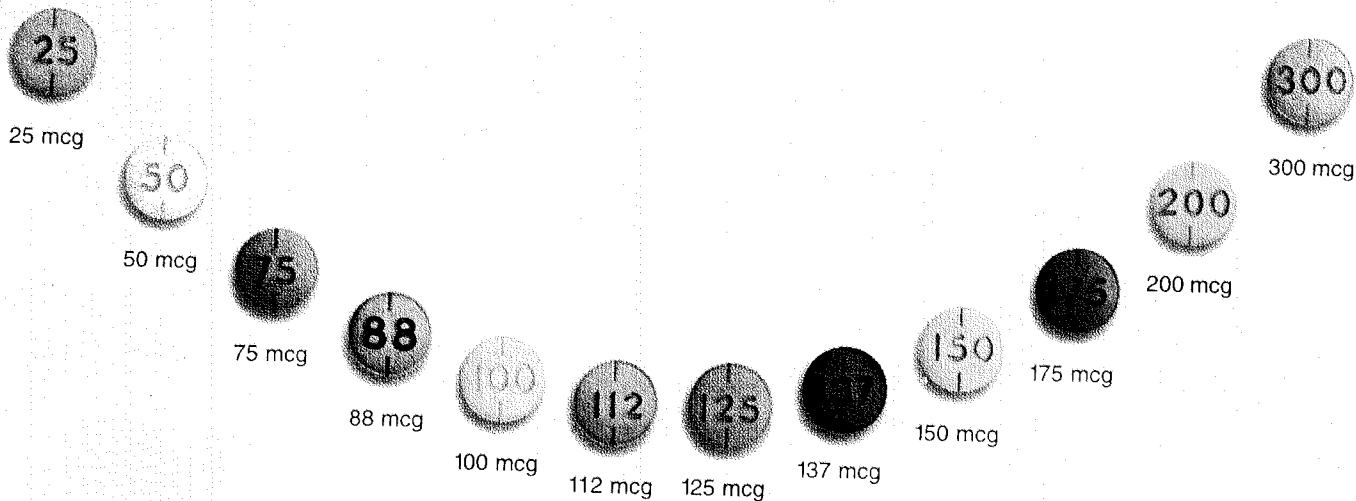
In all future correspondence regarding this particular matter, please refer to MACMIS ID # 9499.

Sincerely,

/S/

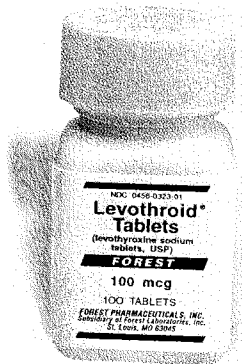
Margaret M. Kober, R.Ph.
Regulatory Review Officer,
Division of Drug Marketing,
Advertising, and Communications

Smile.



Dispense Levothroid® and make your patients smile
with effective LT4 therapy at a great price.

- Levothroid offers you the lowest Average Wholesale Price of the three leading levothyroxines*.
- Levothroid has the widest range of LT4 dosing options available.
- Levothroid provides precise hypothyroidism control through accurate dosing titration for optimum maintenance of thyroid function.
- Levothroid has been proven reliable and consistent with over 30 years of successful use in patients suffering from hypothyroidism.



Levothroid
(levothyroxine sodium tablets, UPS)
Brand-Name Levothyroxine at a Generic Price

*Average Wholesale Price does not represent cost to the pharmacy or cost to the patient. Retail pricing may vary from community to community and may affect cost savings to the patient. Average Wholesale Price (AWP) provided by Red Book Update®, August 2000.

 FOREST PHARMACEUTICALS, INC.
Subsidiary of Forest Laboratories, Inc.
St. Louis, Missouri 63104

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55-110513