



JUN - 9 1997

TRANSMITTED VIA FACSIMILE

Andrew Franz
Executive Vice President of Pharmaceuticals
Jones Medical Industries, Inc.
1945 Craig Road
P.O. Box 46903
St. Louis, MO 63146

RE: Levoxyl (Levothyroxine Sodium Tablets USP)
MACMIS ID # 2380

Dear Mr. Franz:

Reference is made to Jones Medical Industries' (Jones Medical) advertisement for Levoxyl, "FINALLY...An Interchangeable Alternative to Synthroid without loss of therapeutic efficacy." 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: "Finally...An interchangeable alternative to Synthroid without loss of therapeutic efficacy" in conjunction with the statement "Levoxyl...The only branded Levothyroxine recognized as bioequivalent to Synthroid" are misleading because they suggest that Levoxyl is a new product that has been determined to be bioequivalent to Synthroid by an official body such as the Food and Drug Administration. However, levothyroxine products are not currently recognized by the FDA as bioequivalent.
- The statements, "Quality...Levoxyl meets the proposed, more stringent USP Test #2 for dissolution. Synthroid does not," would be misleading because they imply that Levoxyl is of superior quality to Synthroid based on differences in dissolution profile. However, no correlation has been

established between in vitro dissolution and human bioavailability for any levothyroxine products. Thus, the clinical significance of differences in dissolution profiles is not known.

- The statement, "Dependability...Levoxyl has a spotless recall record. Synthroid does not," is misleading because it implies superior safety of Levoxyl versus Synthroid in the absence of adequate supporting data.
- The statement, "Flexibility...Levoxyl has a wider range of potencies than Synthroid," is misleading because it suggests that Levoxyl is superior to Synthroid in terms of tablet potency in the absence of adequate data. Further, the fact that Levoxyl has an additional dosage strength does not equate to the claim that Levoxyl has "a wider range of potencies."
- The statements, "Levoxyl is the least expensive brand name of levothyroxine. Synthroid is approximately twice the cost" are misleading because retail pricing varies from community to community and may affect cost savings to patients. For many patients, there may be no price difference, depending on insurance coverage.

Therefore, DDMAC requests that Jones Medical immediately discontinue this advertisement and all other promotional materials with similar issues. DDMAC requests that Jones Medical submit a written response by June 23, 1997, indicating your intent to comply with this recommendation.

If Jones Medical 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.

Andrew Franz
Levoxyl

Page 3

In all future correspondence regarding the materials discussed in this letter, please refer to MACMIS ID #2380 in addition to the NDA number.

Sincerely,

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