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FEB 1 1999

TRANSMITTED VIA FACSIMILE

Nancy Cafmeyer
Regulatory Affairs
Jones Medical Industries, Inc.
1945 Craig Road
P.O. Box 46903
St. Louis, Missouri 63146

**RE: Levoxyl (levothyroxine sodium tablets, USP)
MACMIS # 6649**

Dear Ms. Cafmeyer:

This letter addresses Jones Medical Industries, Inc.'s (Jones') dissemination of a journal advertisement for Levoxyl, entitled "Take A Closer Look," that was published in Pharmacist magazine in September 1998. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement as part of its monitoring and surveillance program. DDMAC has concluded that Jones' advertisement is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations.

Specifically, DDMAC objects to the statement that "Levoxyl is **interchangeable** with Synthroid . . ." since it suggests that Levoxyl is a levothyroxine drug product that has been determined to be bioequivalent to Synthroid by the U.S. Food and Drug Administration (FDA). Levoxyl and Synthroid are brand name levothyroxine sodium product. However, neither product has been demonstrated to FDA to be either equivalent to the other or inequivalent to the other. Thus any claims of equivalence are unsupported.

Levothyroxine drug products, such as Levoxyl and Synthroid, are not generally recognized as safe and effective and are not currently recognized by FDA as bioequivalent. No levothyroxine sodium drug product appears in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). For more information about the legal status of these products, we refer you to 62 Fed. Reg.

43535-38 (August 14, 1997) (Prescription Drug Products; Levothyroxine Sodium).

In order to address the objections cited in this letter, DDMAC suggests that Jones take the following actions:

(1) Immediately discontinue the dissemination of this advertisement and all other promotional materials for Levoxyl bearing the same or similar violative presentations upon receipt of this letter.

(2) Provide to DDMAC, in writing, Jones' commitment to comply with number one above.

Jones' response should be received no later than February 12, 1999. If Jones has any questions or comments, please contact the undersigned or Jayne Peterson, R.Ph., J.D., by facsimile at 301-594-6771, or in writing at the Division of Drug, Marketing, Advertising, and Communications, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all correspondence related to this matter, please refer to MACMIS #6649.

Sincerely,

Lesley R. Frank, Ph.D., J.D.
Regulatory Counsel,
Division of Drug Marketing, Advertising,
and Communications