DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG - 1 1997

TRANSMITTED VIA FACSIMILE

Robert Ashworth, Ph.D.
Director, Regulatory Affairs
Knoll Pharmaceuticals
199 Cherry Hill Road
Parsippany, NJ 07054

RE: Synthroid
MACMIS ID # 5632

Dear Dr. Ashworth:

Reference is made to Knoll Pharmaceutical Company (Knoll's) advertisements for Synthroid. These advertisements contain the claims "Synthroid The Measure of Excellence in Thyroid Hormone Replacement Therapy" and "The Rule in Dispensing Thyroid Hormone Replacement." The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these advertisements and finds them 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 headlines "Synthroid, The Measure of Excellence in Thyroid Hormone Replacement Therapy" and "The Rule in dispensing Thyroid Hormone Replacement," and the graphic of a large ruler are misleading because they suggest that Synthroid is the reference standard by which levothyroxine products are measured. These ads also contain reference to FDA determinations in bulleted statements under these headlines, suggesting that this standard or "measure" was a determination made by the agency. However, neither Synthroid nor any other levothyroxine product is currently recognized by the FDA as a reference product or standard for levothyroxine products.

- The claims "There is no substitute for Synthroid," "FDA has not determined bioequivalence among levothyroxine sodium products," "No AB rating according to the FDA Orange Book," and "No proven bioequivalent product" are misleading. These claims suggest that Synthroid is the standard for levothyroxine products; that it is superior to other levothyroxine products; and that no other levothyroxine product is equivalent to or useful in place of Synthroid. However, Knoll fails to reveal facts material to such representations. For example, such facts material to Knoll's representations include information that such determinations have not been made by FDA because the information and applications necessary to make such a determinations have not been submitted to the agency. We also note that at least some data comparing the bioequivalence of Synthroid and other levothyroxine products is under the control of Knoll, but that Knoll has not made the data available for independent review by FDA.

Accordingly, DDMAC has determined that the dissemination of these misleading advertisements by Knoll causes Knoll's product, Synthroid, to be misbranded. Knoll should immediately discontinue these advertisements and all other promotional materials that contain similar issues or themes. DDMAC requests that Knoll submit a written response by August 15, 1997 and include a list of all materials that have been discontinued.

If Knoll 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 #5632 in addition to the NDA number.

Sincerely,

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