



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Dennis M. Jones
President
Jones Pharma Incorporated
1945 Craig Road
P.O. Box 46903
St. Louis, MO 63146

JAN 21 2000

RE: Levoxyl (levothyroxine sodium tablets, USP)
MACMIS ID# 8425

WARNING LETTER

Dear Mr. Jones:

This Warning Letter concerns an advertisement for Levoxyl, by Jones Pharma Incorporated, entitled "Take a Closer Look" that was published in the Program and Abstract Book for the 72nd Annual Meeting of the American Thyroid Association in Palm Beach, Florida on September 29, 1999 – October 3, 1999. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has concluded that this advertisement is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. See 21 U.S.C. §§ 321(n), 331(a)(b), and 352(n).

Background

Levoxyl is a branded levothyroxine sodium product, however, it is not the subject of an approved New Drug Application (NDA). Currently, there are no levothyroxine products in the reference "Approved Drug Products with Therapeutic Equivalence" (FDA's "Orange Book") because Levoxyl, Synthroid, and other levothyroxine products are not approved products. None of these products have been determined to be equivalent to any other or inequivalent to any other. Thus, any claims of equivalence are unsupported. For more information about the status of these products, we refer you to 62 Fed. Reg. 43535-38 (August 14, 1997) (Prescription Drug Products; Levothyroxine Sodium).

On February 1, 1999, DDMAC issued an untitled letter to Jones Medical (now Jones Pharma Incorporated) stating that the Jones' advertisement entitled "Take a Closer Look" that was published in Pharmacist magazine in September, 1998 was in violation of the Act and applicable regulations. Specifically, DDMAC objected to the statement that "Levoxyl is interchangeable with Synthroid" since it suggested that the two drugs are bioequivalent. In a March 31, 1999 letter to DDMAC, Jones indicated it would discontinue use of this and similar promotional material. Based upon your March 31 letter, DDMAC, in its April 8, 1999 letter, closed the matter. Notwithstanding Jones' representation to DDMAC that this and similar promotional pieces would be discontinued, Jones has published a virtually identical advertisement in the Program and Abstract Book for the 72nd Annual Meeting of the American Thyroid Association in September- October, 1999.

False or Misleading Claims

The promotional statement in your advertisements that "Levoxyl is interchangeable with Synthroid" suggests that the two drugs are bioequivalent. However, Levoxyl and Synthroid are not considered interchangeable because the bioequivalency of these products has not been proven. Based on the findings by FDA in the Federal Register notice of August, 1997, the representation by Jones in the September-October, 1999 advertisement that Levoxyl and Synthroid are interchangeable is unsupported.

Conclusion and Recommendation

Jones Pharma's continued dissemination of advertisements that promote Levoxyl as "interchangeable with Synthroid" create false or misleading impressions regarding the current status of levothyroxine sodium drug products. Accordingly, Jones Pharma should propose an action plan to disseminate corrective messages about this issue to all healthcare providers, institutions, and organizations who received this violative promotional material.

This corrective plan should include:

- A. Immediate discontinuation of the dissemination of these advertisements and all other promotional materials that contain the same or similar violations.
- B. A written statement of Jones Pharma's intent to comply with "A" above.

- C. Submission of a proposed "Dear Healthcare Provider" letter that will correct the false or misleading information you disseminated. This letter will be reviewed by DDMAC. After agreement is reached on the content and audience, the letter should be disseminated by direct mail.
- D. Submission of a complete list of all advertising and promotional labeling materials that you intend to continue using and samples of each piece, in duplicate.

The violations discussed in this letter are not intended to be a complete listing. We will continue to evaluate all aspects of your promotional campaigns, and additional violations may be identified. Consequently, we may determine that additional remedial measures may be necessary at a later date to fully correct the false impressions resulting from your improper conduct.

Your response should be received by DDMAC on or before February 5, 2000. If you have any questions about this letter, please contact Margaret M. Kober, RPh. or Lesley R. Frank, Ph.D., J.D., 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 #8425. Failure to respond to this letter may result in regulatory action, including seizure or injunction, without further notice.

Sincerely,

/S/

Norman A. Drezin, R.Ph., J.D.
Acting Director,
Division of Drug Marketing,
Advertising and Communications

Take A closer Look

Levoxyl® (Levothyroxine Sodium Tablets, USP) is the brand name levothyroxine with "benefit" written all over it. Here are just a few of the reasons that Levoxyl® is the fastest growing levothyroxine therapy and the 40th most dispensed¹ medication in the United States.

Levoxyl® is interchangeable with Synthroid® without loss of therapeutic efficacy in the majority of patients for the treatment of hypothyroidism.^{2,3}

Levoxyl® boasts a spotless recall record. A standard of excellence achieved through 11 years of consistent manufacturing and testing. Quality proven time and time again.

Jones Pharma Incorporated is committed to providing a high quality levothyroxine product at substantial savings to you and your patients.⁴

Take a closer look at Levoxyl®. A brand name you can trust, a brand with the "benefits" you expect.

(See accompanying full prescribing information)

JONES PHARMA INCORPORATED
ENDOCRINE DIVISION



'YOUR THYROID COMPANY'

www.jmedpharma.com

¹American Druggist, February 1993.

²JAMA, April 16, 1997.
³Bioequivalence of Generic and Brand-name Levothyroxine Products in the Treatment of Hypothyroidism. Results are not directly applicable to patients receiving thyroxine suppression therapy.

⁴THE FDA HAS NOT DETERMINED BIOEQUIVALENCE AMONG LEVOTHYROXINE PRODUCTS.

⁵Cost comparison is based on average wholesale price (AWP) as published in the 1999 Drug Topics Red Book and may not represent actual prices to specific pharmacies or consumers.

LEVOXYL® IS A REGISTERED TRADEMARK OF JONES MEDICAL INDUSTRIES, INC.

SYNTHROID® IS A REGISTERED TRADEMARK OF ANO-LI PHARMACEUTICAL COMPANY.