CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-924

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-924

Institute Biochimique SA (IBSA)
Attention: Clarence E. Jones, Ph.D.
U.S. Agent
8602 Mossford Drive
Huntington Beach, CA 92646

Dear Dr. Jones:

Please refer to your new drug application (NDA) dated November 30, 2005, received December 5, 2006, pursuant to section 505(b)(2) submitted of the Federal Food, Drug, and Cosmetic Act for Tirosint™ (levothyroxine sodium capsules), 25, 50, 75, 100, 125, and 150 mcg.

We acknowledge receipt of your submissions dated December 13 and 20, 2005, March 30, June 27, August 29, and September 14, 2006.

This new drug application provides for the use of Tirosint as replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, or in the treatment or prevention of various types of euthyroid goiters, as an adjunct to surgery and radioiodine therapy in the management of thyrotripin-dependment well differentiated thyroid cancer.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

This levothyroxine product has been approved under the current USP potency specifications of 90 - 110%. However, based on the outcome of the October 4, 2006, joint meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Science, the Agency is taking under consideration the committees' recommendation that the potency specifications for all levothyroxine products be narrowed to 95 - 105%. Should the potency specifications be narrowed, you are informed that your product may require a change in expiry or a change in formulation.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) dated September 14, 2006, immediate container and carton labels (submitted September 14, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-924.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/The Division of Metabolism and Endocrinology Products, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Project Manager, at 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (package insert)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks
10/13/2006 04:02:07 PM