CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-905

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-905

Parexel International Corporation
Agent for LG Life Sciences, Ltd.
Attention: Alberto Grignolo, Ph.D.
200 West Street
Waltham, MA 02451-1163

Dear Dr. Grignolo:

Please refer to your new drug application (NDA) dated November 30, 2005, received December 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtropin® (somatropin [rDNA origin] 5 mg for injection, USP).

We acknowledge receipt of your submissions dated October 26, and December 20, 2006, and February 16, 2007.

The February 16, 2007, submission constituted a complete response to our November 8, 2006, action letter.

This new drug application provides for the use of Valtropin (somatropin [rDNA origin] 5 mg for injection, USP), for the treatment of children with growth failure due to inadequate secretion of endogenous growth hormone, for the treatment of short stature in children with Turner Syndrome, and as replacement therapy in adults with growth hormone deficiency (GHD) of either childhood or adult onset.

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.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), dated December 20, 2006, and text for the immediate carton, container and diluent submitted February 16, 2007. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

In addition, we strongly recommend the following:

- That you develop a safety database for both children and adults treated with Valtropin similar in design to the safety databases maintained by multiple other sponsors approved to market somatropin formulations;

- That you add an additional section to your annual Periodic Safety Update Report (PSUR) wherein the incidences of all AEs (in particular, diabetes mellitus, benign intracranial hypertension, slipped capital femoral epiphysis, aggravation of preexisting scoliosis, recurrent otitis media and hypertension) are compared in Turner Syndrome children and non-Turner Syndrome children treated with Valtropin;

- That you attempt to capture final height data on the Turner Syndrome patients and children with GHD who were treated with Valtropin in Studies BP-EU-002 and BP-EU-003, respectively.

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 21-905."** 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, Regulatory 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: insert labeling

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
4/19/2007 07:29:24 AM