CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-905

APPROVABLE 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] for Injection, USP).

We acknowledge receipt of your submissions dated December 13, 2005, February 7, April 28, May 26, July 18, and August 4, 11, and 30, and September 21, 2006.

We also acknowledge receipt of your submission dated October 26, 2006. This submission was not reviewed for this action. You may incorporate this submission by specific reference as part of your response to the deficiencies cited in this letter.

We completed our review of this application as submitted with final printed labeling (FPL) for the package insert (dated October 26, 2006), immediate drug product vial container and diluent vial container (dated October 26, 2006), and carton label (dated November 30, 2005), and it is **approvable.** Before the application may be approved, however, it will be necessary for you to obtain an acceptable establishment evaluation.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division, Division of Metabolism and Endocrinology Products to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

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

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
11/8/2006 02:02:22 PM