DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-538 **NDA APPROVAL**

Chesapeake Biological Laboratories, Inc.
US Agent for Cangene Corporation
Attention: Minerva Devera
Director of Quality Assurance and Regulatory Affairs
Camden Industrial Park, 1111 S. Paca Street
Baltimore, MD 21230-2591

Dear Ms. Minerva:

Please refer to your new drug application (NDA) dated May 9, 2006, received May 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Accretropin (somatropin [rDNA origin]) Injection, 5 mg/ml.

We acknowledge receipt of your submissions dated March 27, April 23, July 20, 2007, and January 9, 2008.

The July 20, 2007 submission constituted a complete response to our March 8, 2007 action letter.

This new drug application provides for the use of Accretropin (somatropin [rDNA origin]) Injection for:

1. treatment of pediatric patients who have growth failure due to an inadequate secretion of normal endogenous growth hormone.
2. treatment of short stature associated with Turner syndrome in pediatric patients whose epiphyses are not closed.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-538."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 23, 2007 submission containing final printed carton and container labels.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

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, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert
Vial Label
Carton Label

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

1/23/2008 07:00:38 PM