# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**21-538**

## OTHER ACTION LETTER(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-538

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. Devera:

Please refer to your new drug application (NDA) dated May 9, 2006, received May 10, 2006, 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 May 9, June 12 and 21, September 6, 2006, January 22, 26 and 29, February 5 (2 submissions), 9 and 26, 2007.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to address the following:

b(4)

# 1 Page(s) Withheld

X Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

*Withheld Track Number: Other Action Letters-*_____

b(4)

9. Environmental monitoring program: Please describe the actions that are taken when any environmental monitoring levels (for example, water, viable and non-viable particulates) are exceeded.

Labeling will discussed at a later date.

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 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

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. 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.

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

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 and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

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/s/

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Mary Parks
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