DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-355/S-007

CSL Behring LLC
Attention: Paul R. Hartman, R.Ph.
Senior Director, Regulatory Affairs
1020 First Avenue, P.O. Box 61501
King of Prussia, PA 19406-0901

Dear Mr. Hartman:

Please refer to your supplemental new drug application dated October 27, 2006, received October 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Stimate (desmopressin acetate) Nasal Spray, 1.5 mg/mL.

We acknowledge receipt of your submissions dated January 10 and July 20, 2007.

This supplemental new drug application provides for a change in storage conditions to room temperature from the current refrigerated storage. This change consists of a reformulation to support stability at room temperature.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for package insert and patient instruction guide submitted on July 20, 2007). We note that content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format was submitted on July 20, 2007.

Submit final printed carton, immediate container, package, and shipper labels that are identical to the enclosed carton, immediate container, package, and shipper labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton, Container, Package and Shipper Labels for approved NDA 20-355/S-007**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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

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

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

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 Jennifer Johnson, Regulatory Project Manager, at (301) 796-2194.

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, Patient Instruction Guide, Carton Label, Immediate Container Label, Package Label and Shipper Label

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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.

/s/

Mary Parks

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