DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-807/SLR-011

Berlex, Inc.
Attention: Claudia Hernandez
340 Changebridge Road
PO Box 1000
Montville, NJ 07045

Dear Ms. Hernandez:

Please refer to your supplemental new drug application dated November 8, 2005, received November 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Refludan® [lepirudin (rDNA)] for Injection.

We acknowledge receipt of your submissions dated May 8, May 25, July 27 and August 11, 2006.

Your submission of May 25, 2006 constituted a complete response to our May 9, 2006 action letter.

This supplemental new drug application provides for revising the DOSAGE AND ADMINISTRATION section of the package insert to add a subsection entitled "Use in Patients Scheduled for a Switch to Oral Anticoagulation".

We 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 agreed-upon labeling text.

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 to the enclosed labeling text/submitted labeling dated May, 25, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website. In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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 Patricia Stewart, Regulatory Project Manager, at (301) 796-1469.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D.
Director
Division of Medical Imaging and
Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

George Mills
11/7/2006 06:17:43 PM