



NDA 20-807/SLR-015

Berlex, Inc.
Attention: Maria C. Garrigan
Director, Global Regulatory Affairs
PO Box 1000
Montville, NJ 07045-1000

Dear Ms. Garrigan:

Please refer to your supplemental new drug application dated September 11, 2006, received September 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Refludin® [lepirudin (rDNA) for injection].

We acknowledge receipt of your submissions dated January 10 and March 5, 2007.

This “Changes Being Effectuated in 30 days” supplemental new drug application provides for changes to the package insert and carton and vial labeling based on comments from the Division of Medical Errors and Technical Support (DMETS) to address concerns with reported medication errors.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels) and/or submitted labeling (package insert submitted March 5, 2007, immediate container and carton labels submitted March 5, 2007).

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).

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If you have any questions, call Patricia A. Stewart, Regulatory Project Manager, at (301) 796-1469.

Sincerely,

{See appended electronic signature page}

Rafel Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology
Products
Office of Oncology 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/

Rafel Rieves

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