DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-807/S-005

Berlex Laboratories, Inc.
Attention: Brenda Marczi, Pharm.D.
340 Changebridge Road, P.O. Box 1000
Montville, NJ 07045-1000

Dear Dr. Marczi:

Please refer to your supplemental new drug application October 7, 2002, received October 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rufludan® [lepirudin (rDNA)] for Injection.

This "Changes Being Effected" supplemental new drug application provides for revising the package insert to revise the WARNINGS and ADVERSE REACTIONS sections of the package insert.

In addition, we note that your supplement also contained a "Dear Health Care Practitioner" (DHCP) letter. Please refer to our October 24, 2002 supplement acknowledgement letter in which we notified you that we had administratively split the DHCP letter out from the supplement and made it into a separate submission and would responding separately to the DHCP letter. We are responding to the DHCP letter under separate cover.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon final printed labeling submitted October 7, 2002.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Alice Kacuba, MSN, RN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick

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