DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-0345/S-001

Fonda BV
Attention: Richard P. Gural, Ph.D.
Vice President, Regulatory Affairs
9 Great Valley Parkway
P.O. Box 3026
Malvern, PA 19355

Dear Dr. Gural:

Please refer to your supplemental new drug application dated June 3, 2002, received June 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ARIXTRA® (fondaparinux sodium) Injection, 2.5 mg.

We acknowledge receipt of your submissions dated July 9, November 4, November 29 (telefacsimile), December 2 (telefacsimile), 3 (telefacsimile), and December 4 (2) (telefacsimile), 2002.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** section, **Clinical Studies** subsection, **PRECAUTIONS** section and the **ADVERSE REACTIONS** section of the package insert (PI).

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) which was submitted on December 4, 2002.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 21-345/S-001**." Approval of this submission by FDA is not required before the labeling is used.

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 Diane Moore, Regulatory Project Manager, at (301) 827-7476.

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

Enclosure:

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

/s/

Robert Justice

12/4/02 06:29:00 PM