DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-484/S-006

Pharmion Corporation
Attention: Deborah W. Tady, Pharm.D., R.Ph., M.B.A.,
Manager, Regulatory Affairs
9900 West 109th Street, Suite 300
Overland Park, KS 66210

Dear Dr. Tady

Please refer to your supplemental new drug application dated July 29, 2005, received August 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Innohep® (tinzaparin sodium injection).

We acknowledge receipt of your submissions dated May 5 and November 3, 2006.

Your submission of May 5, 2006 constituted a complete response to our February 1, 2006 action letter.

This supplemental new drug application provides for revisions to the Innohep package insert to include information derived from the pharmacokinetic/pharmacodynamic study entitled "A Multicenter, Prospective, Open, Uncontrolled Dose-finding Study of Tinzaparin Conducted in Pregnant Women to Evaluate Human Pharmacokinetics and Pharmacodynamics."

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) and submitted labeling (package insert submitted November 3, 2006).

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 Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

George 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/

Rafel Rieves

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