DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 18 1997

TRANSMITTED VIA FACSIMILE

Ronald F. Panner
Director Regulatory Affairs
Rhone-Poulenc Rorer Pharmaceuticals, Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426

Re: **NDA 20-164**
Lovenox (enoxaparin sodium)
MACMIS File ID #5611

Dear Mr. Panner:

This letter is in reference to Rhone-Poulenc Rorer Pharmaceuticals, Inc.'s (RPR) submission of promotional materials under cover of FDA Form 2253 for Lovenox (enoxaparin sodium) Injection. These materials included a promotional poster and a flip-chart display. The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards these posters to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

Specifically, DDMAC is concerned that RPR makes claims that "safety comparable to placebo in hip- and knee-replacement surgery." The statement that enoxaparin is comparable to placebo in safety is lacking in fair balance or otherwise misleading in violation of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder. DDMAC's specific objection is that this statement is misleading in that it does not convey the rates of adverse events associated with the use of enoxaparin and placebo observed in clinical trials. Moreover, enoxaparin has warnings concerning the risk of thrombocytopenia and the risk of neuraxial hematomas associated with the concurrent use of neuraxial anesthesia and post-operative indwelling epidural catheters. These are serious risks associated with the use of enoxaparin. It is false and misleading to suggest or imply that there are no serious risks associated with the use of enoxaparin by stating that its safety is comparable to placebo.

RPR should provide written response to DDMAC by July 31, 1997, addressing these concerns. RPR's response should be directed to the undersigned by facsimile at (301) 594-6771, or at the

Division of Drug Marketing, Advertising, and Communications, *HFD-40, 5600 Fishers Lane*, Rockville, Maryland 20857.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 5611 in addition to the NDA number.

Sincerely,

Stephen W. Sherman
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications