DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

Audrey L. Hackman
Manager, Worldwide Regulatory Affairs
Rhone-Poulenc Rorer Pharmaceuticals Inc.
500 Arcola Road
Collegeville, PA 19426-0107

APR 8 1999

RE: **NDA 20-164**
Lovenox® (enoxaparin sodium) injection
MACMIS ID # 6789

Dear Ms. Hackman:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Lovenox® (enoxaparin sodium) injection disseminated by Rhone-Poulenc Rorer Pharmaceuticals Inc. (RPR) that violate the Federal Food Drug and Cosmetic Act (Act) and its implementing regulations. Reference is made to a promotional brochure, identified as MLC990346, which was disseminated at the meeting of the National Managed Health Care Congress (NMHCC) held in Atlanta, Georgia, March 30, 1999. DDMAC has reviewed this material and has determined that it promotes Lovenox® in a manner that is false or misleading.

The promotional brochure includes the comparative claim "Lovenox shortened the mean hospital stay from 6.5 to 1.1 days." This claim represents a comparison between Lovenox® and traditional heparin therapy used to treat patients with acute proximal deep-vein thrombosis. The support provided for this promotional claim is a journal reference by Levine et al.[1] In this study, patients were randomized to receive either low-molecular-weight heparin primarily at home or standard heparin therapy in the hospital. Thus, treatment in the hospital or at home was defined by the protocol. Promotional claims are false or misleading if they represent or suggest that a drug is more effective than has been demonstrated by substantial evidence. Therefore, the claim that Lovenox® decreased the hospital stay for patients in this study would be false or misleading because the claim is not adequately substantiated.

---

1 Levine M, Gent M, Hirsh J, et al. *A comparison of low-molecular-weight heparin administered primarily at home with unfractionated heparin administered in the hospital for proximal deep-vein thombosis.* N Engl J Med 1996;334(11):677-681.

Please refer to our letter dated January 27, 1999, wherein DDMAC commented on this same claim in response to RPR's request for comments. In that letter, DDMAC objected to the use of this claim for the reason stated above. In addition, please refer to RPR's correspondence dated February 26, 1999, responding to DDMAC's comments wherein RPR stated that it agreed to revise this claim and offered an alternate presentation in place of the one above. DDMAC is currently reviewing the alternate proposal. DDMAC is especially concerned about the use of this claim in promotion since RPR was previously informed that this claim would be misleading.

RPR should immediately cease distribution of this and other similar promotional materials for Lovenox® that contain the same or similar claims. RPR should submit a written response to DDMAC on or before April 22, 1999, describing its intent and plans to comply with the above.

RPR should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds RPR that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 6789 and NDA 20-164.

Sincerely,

John C. Markow R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications