DEPARTME OF HEALTH & HUMAN SERVICES

Health Service

Food and Drug Administration
Rockville MD 20857

AUG 7 1997

TRANSMITTED BY FACSIMILE

Kathleen J. Day
Director, Regulatory Affairs, Labeling and Promotion
Pharmacia & Upjohn, Inc.
7000 Portage Road
Kalamazoo, Michigan 49001-0199

Re: **NDA 20-287**
Fragmin (dalteparin sodium)
MACMIS ID # 5664

Dear Ms. Day:

This letter is in reference to Pharmacia & Upjohn, Inc.'s (P&U) submission, dated June 13, 1997, of promotional materials under cover of Form FDA 2253 for Fragmin (dalteparin sodium). This submission consisted of a risk assessment card for surgical patients (USX 8117.00). The Division of Drug Marketing, Advertising, and Communications (DDMAC) considers this risk assessment card to be promoting an unapproved use in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder.

DDMAC's specific objection to this card is that under the risk factors listed that may cause thrombosis following surgery are
Therefore, this card suggests
However, dalteparin's approved product labeling states that it is "indicated for prophylaxis against deep vein thrombosis, which may lead to pulmonary embolism, in patients undergoing abdominal surgery
Thus, this promotional piece would be promoting an unapproved use in violation of the Act.

P&U should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter until these allegations are resolved. P&U should submit a written response to DDMAC on or before August 22, 1997, describing the steps that it has taken to ensure that these activities and the use of these materials have been suspended.

If P&U has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD, 20857.. DDMAC reminds P&U that only written correspondence is considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID # 5664, in addition to the NDA number.

Sincerely,

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