DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

JUN 4 1997

TRANSMITTED VIA FACSIMILE

Alexandra D.J. Mancini, M.Sc.
Vice President, Regulatory Affairs
QLT PhotoTherapeutics Inc.
520 West 6th Avenue
Vancouver, British Columbia
Canada V5Z4H5

RE: NDA #20-451
Photofrin (porfimer sodium)
MACMIS #5464

Dear Ms. Mancini:

The Division of Drug Marketing, Advertising, and Communications has determined that Sanofi Pharmaceuticals, Inc. (Sanofi) is promoting Photofrin for unapproved uses, in violation of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder. Specifically, Sanofi displayed a poster in its booth in the exhibit hall at a recent medical conference. The poster described four unapproved uses of Photofrin, and the development status for each. This activity constitutes promotion of unapproved uses of Photofrin.

QLT/Sanofi should immediately cease this and all similar promotional activities that promote Photofrin for unapproved uses. QLT should reply in writing, regarding its intent and plan to comply with the above. QLT's response should be received by DDMAC no later than June 16, 1997, and should be addressed to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds QLT that only written communication is considered official.

In all correspondence regarding this particular matter, please refer to MACMIS #5464 in addition to the NDA number.

Sincerely,

Tracy Acker

Tracy Acker, Pharm.D.
Regulatory Review Officer
Division of Drug, Marketing,
Advertising, and Communications

cc: Robert Mandetta, Sanofi Pharmaceuticals Inc.