DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

FEB 26 1998

Helen Shu, Ph.D.
Senior Director, Regulatory Affairs
Neurex Corporation
3760 Haven Avenue
Menlo Park, CA 94025-1012

RE: **NDA 19-922**
Corlopam (fenoldopam mesylate) Injection
MACMIS ID # 5980

Dear Dr. Shu:

This letter is in response to Neurex Corporation's (Neurex) letter, dated February 9, 1998, concerning a journal ad for Corlopam (fenoldopam mesylate) injection. This journal ad contains the statement that Corlopam provides "precise control," a claim that previously had been determined by the Division of Drug Marketing, Advertising and Communications (DDMAC) to be false and/or misleading during review of proposed introductory materials. Reference is made to Neurex's submission of proposed promotional materials, dated October 30, 1997, November 24, 1997, November 26, 1997, December 10, 1997, December 12, 1997, December 19, 1997, and January 7, 1998, DDMAC's comments, dated November 14, 1997, December 5, 1997, December 12, 1997, December 18, 1997, December 29, 1997, and January 22, 1998, as well as a teleconference between Neurex and DDMAC on November 26, 1997.

Reference is also made to a telephone conversation between DDMAC (Janet Norden) and Neurex (Helen Shu) on January 29, 1998. In this conversation, Neurex notified DDMAC that the journal ad had inadvertently been released and that it has been subsequently discontinued. In your letter, dated February 9, 1998, Neurex provided a list of the publications that were already released with the claim "precise control."

DDMAC acknowledges your bringing this matter to our attention and has reviewed your actions taken in response to this issue. In light of your discontinuation of this journal ad, DDMAC considers this matter closed.

If you have any further 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, Maryland 20857. DDMAC reminds Neurex that only written communications are considered official.

In all correspondence regarding this particular submission, please refer to MACMIS ID #5980, in addition to the NDA number.

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications