DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 23, 2000

Bruce Ronsen, Ph.D.
Pentech Pharmaceuticals, Inc.
1110 Lake-Cook Road
Buffalo Grove, IL 60089

00 JUN 26 A9:47

Re: Docket No. 00P-0090/CP1

Dear Dr. Ronsen:

This responds to your citizen petition, dated December 28, 1999, requesting that the Food and Drug Administration (FDA) determine whether paroxetine hydrochloride 10-, 20-, 30-, and 40-mg capsules were withdrawn or withheld from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that paroxetine hydrochloride 10-, 20-, 30-, and 40 mg capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain paroxetine hydrochloride 10-, 20-, 30-, and 40 mg capsules in the "Discontinued Drug Product List" of the *Approved Drug Products with Therapeutic Equivalence Evaluations*.

Enclosed is a copy of the *Federal Register* notice announcing FDA's determination. If you require any further information, please do not hesitate to call me at 301-594-2041.

Sincerely yours,

Mary Catchings

Mary Catchings
Regulatory Policy Staff (HFD-7)
Center for Drug Evaluation and Research

Enclosure

00P-0090

ANSI