DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 14-134/S-024

Wyeth Pharmaceuticals
Attention: Ms. Nanette Holston
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Holston:

Please refer to your supplemental new drug application dated July 30, 2002, received August 2, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protopam® (pralidoxime chloride) for Injection.

This supplemental new drug application provides for revision of the PRECAUTIONS section of labeling to add a "Geriatric Use" subsection in accordance with 21 CFR 201.57(f)(10).

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

We note that your submssion includes at Tab F a copy of the package insert dated December 11, 2001 that is marked as the "Currently Approved Package Insert (CI 7544-1)". We also note that this package insert includes a statement that (b)----------D is the manufacturer of your drug product. Additionally, we note that the draft labeling included at Tab A of your submission includes this change. Our records do not indicate that this version of the package insert has ever been approved.

Although a "prior approval" manufacturing and controls supplemental application has been submitted to provide for this change (S-025 dated August 8, 2002), we have yet to act upon that application. Therefore, we have revised the attached labeling to remov(b)----------D as the manufacturer of your drug product at this time.

Please note that you may make this change in labeling and report it to us in the next annual report after final approval of pending supplemental application S-025.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30

days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 14-134/S-024." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Mr. Robbin Nighswander, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
9/27/02 04:20:25 PM