DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 14-879/S-036

Wyeth-Ayerst Research
Box 8299
Philadelphia, PA 19101-8299

Attention: Nanette E. Holston
Director, World Wide Regulatory Affairs

Dear Ms. Holston:

Please refer to your supplemental new drug application dated January 10, 2001, received January 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopram (doxapram hydrochloride injection, USP) Injectable.

We acknowledge receipt of your submission dated February 14, 2001.

This "Changes Being Effected" supplemental new drug application updates the label based on the December 13, 1994, Federal Register: Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of "Pediatric Use" Subsection in the Labeling.

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 submitted final printed labeling (package insert submitted January 10, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

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, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research