DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 10-996/S-061
NDA 10-997/S-043
NDA 16-862/S-033

Lilly Reasearch Laboratories
Attention: Timothy Franson, M.D.
Executive Director North American Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Franson:

Please refer to your supplemental new drug applications dated June 11, 1996, and June 14, 1996, received June 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Darvon Compound 65 (propoxyphene hydrochloride, aspirin and caffeine) Capsule, Darvon (propoxyphene hydrochloride) Capsules, Darvon N (propoxyphene napsylate) Tablets.

These supplemental new drug applications provide for changes to the **HOW SUPPLIED** and **Other Infromation** sections of the label.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are 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 Carmen DeBellas, Chief Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Lee S. Simon. M.D.
Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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

/s/

Lee Simon
8/1/02 12:00:53 PM