DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 15-539/S-052

Faulding, Inc.
Attention: Joan Janulis, R.A.C.
Vice President, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Ms. Janulis:

Please refer to your supplemental new drug application dated August 27, 1998, received August 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serax® (oxazepam) Tablets 15 mg, and Capsules 10 mg, 15 mg, and 30 mg.

We acknowledge receipt of your submission dated October 11, 2000, which constituted a complete response to our June 22, 2000 action letter.

This supplemental new drug application provides for the addition of a geriatric use subsection to PRECAUTIONS and new geriatric language to CLINICAL PHARMACOLOGY.

We have completed the review of this supplemental application, as amended, 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 October 11, 2000). 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 should have any questions, please call Ms. Anna Marie Homonnay, R.Ph., Regulatory Project Manager, at (301) 594-5535.

Sincerely,

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