DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 12003/S-024

Abbott Laboratories
Attention: Ernesto J. Rivera
Regulatory Affairs Project Manager
200 Abbott Park Road
D-491/AP30-IE
Abbott Park, IL 60064-6108

Dear Mr. Rivera:

Please refer to your supplemental new drug application dated December 27, 2001, received December 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Akineton (biperiden) Tablet 2 mg.

This "Changes Being Effected" supplemental new drug application provides editorial and labeling changes requested in our July 23, 2001 approval letter.

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 December 27, 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 Teresa Wheelous, 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

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
2/4/02 08:38:23 AM