DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-462/S-042
12-699/S-036

G.D. Searle LLC/Pfizer Inc
Attn: Robert Clark
Vice President, US Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Mr. Clark:

Please refer to your supplemental new drug applications dated October 31, 2005, received November 02, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lomotil (diphenoxylate hydrochloride and atropine sulfate) Tablets 2.5 and 0.025 mg and Lomotil (diphenoxylate hydrochloride) Liquid 2.5 and 0.025 mg.

We acknowledge receipt of your submissions dated December 02, 2005.

These "Changes Being Effected" supplemental new drug applications provide for the following:

- a change, in accordance with FDA's supplement request letter dated August 1, 2005, to remove from the product label the following statement:

  "The recommended dosage for children 13-16 years: 2 tablets or two 5 ml liquid measures three times daily."
- a change in the company signature line and internal coding
- an update to the established name in accordance with USP

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert) from the December 02, 2005 submission.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Giuseppe Randazzo, Regulatory Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., MPH
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Joyce Korvick

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