



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-487/S-022

McNeil Consumer & Specialty Pharmaceuticals
Attention: Victoria Wagner-Weber
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Wagner-Weber:

Please refer to your supplemental new drug applications submitted March 5, 2004, received March 8, 2004, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for: Imodium® A-D (loperamide HCL) Liquid.

We also acknowledge receipt of your submissions dated June 9, June 30, July 1, and July 7, 2004.

This supplemental application proposes a reformulation of Imodium A-D liquid to an opaque, green liquid with a mint flavor.

We have completed our review of this application, as amended. This application is 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 approved draft labeling (carton label principal display panel submitted March 5, 2004, and Drug Facts panel submitted July 1, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66.

We remind you to remove the phrase "NEW FORMULA" from the product labels after 180 days of OTC marketing.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely yours,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.

Deputy Director

Division of Over the Counter 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
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/s/

Brian Harvey
7/8/04 01:13:40 PM
Signed for Dr. Curtis Rosebraugh.