DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-487/S-021
NDA 19-860/S-020
NDA 20-606/S-009
NDA 21-140/S-003

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 December 15, 2003, received December 16, 2003, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for: Imodium® A-D (loperamide HCL) Liquid, Imodium (loperamide HCL/simethicone) Caplets, Imodium Advanced (loperamide HCL/simethicone) Chewable Tablets, Imodium Advanced (loperamide HCL/simethicone) Caplets.

We also acknowledge receipt of your submissions dated March 29, 2004, and June 11, 2004.

These supplemental applications propose revised labeling under the "Stop use and ask a doctor if" and "Other information" sections.

We have 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 approved draft labeling (carton label submitted June 11, 2004) and must be formatted in accordance with the requirements of 21 CFR 201.66. We noted that the subheading "**When using this product**" does not appear in bold type in the approved draft labeling. We remind you to use bold type for all headings and subheadings (21 CFR 201.66 (d)(3)) .

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 this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh
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