



NDA 19-487/S-023

McNeil Consumer & Specialty Products
Attention: Carolyn Zlogar
Manager, CMC Regulatory
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Zlogar:

Please refer to your supplemental new drug application dated December 22, 2004, received December 23, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium A-D (loperamide HCL) Liquid.

This supplemental new drug application proposes a new 12 oz bottle package size and the addition of a (b) (4) production batch.

We have completed our review of this application. 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 submitted labeling (immediate container label submitted on December 22, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-487/S-023.**" Approval of this submission by FDA is not required before the labeling is used.

We also recommend the following labeling changes. These changes are not a condition of approval. You may incorporate these changes in the labeling at the next time of printing and submit the revised labeling in the following annual report.

1) Vertically align the bulleted statements in the, "**Stop use and ask a doctor if**" and "**Directions**" sections according to 21 CFR 201.66(d)(4), so that the bulleted statements appearing on each subsequent horizontal line of text under a heading or subheading are vertically aligned with the bulleted statements appearing on the previous line.

2) Move the statement "**Keep out of reach of children**" to a new line, in alignment with the other left justified Drug Facts headings to conform with 21 CFR 201.66(b)(7) and (d)(1).

If you issue a letter communicating important information about this drug product (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 LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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
6/8/05 07:51:04 AM