



NDA 17-694/S-050

McNeil Consumer & Specialty Pharmaceuticals
Attn: Hina S. Wu, Pharm.D.
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Dr. Wu:

Please refer to your supplemental new drug application dated April 20, 2005, received April 22, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium[®] (loperamide HCL) Capsule, 2 mg.

Your submission of April 20, 2005 constituted a complete response to our December 21, 2004 action letter.

This supplemental new drug application provides for revised labeling in response to our December 21, 2004, approvable letter.

We 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 and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated in the enclosed labeling text for the package insert. These revisions are terms of the approval of this application.

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 17-694/S-050.**" Approval of this submission by FDA is not required before the labeling is used.

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}

Brian E. Harvey, M.D. Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and research

Enclosure

**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
10/21/2005 02:41:59 PM
for Dr. Brian Harvey