DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19860/S-018

McNeil Consumer Health Care
Attention: Mrs. Paula Oliver
Senior Director, Regulatory Compliance
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Mrs. Oliver:

Please refer to your supplemental new drug application dated April 13, 2000, received April 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium A-D Caplets. We acknowledge receipt of your submissions dated October 3, 2000 and January 10, 2001.

This supplemental new drug application provides for the formatting of existing labeling into Drug Facts format.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

1. The tamper evident statement in the labeling "**do not use if carton or blister unit is open or torn**" needs to be bolded.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (immediate container and carton labels submitted January 10, 2001 and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19860/S-018." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Daniel P. Keravich, RPh., MS., MBA., at (301) 827-2248.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, 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