DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-140/S-002

McNeil Consumer & Specialty Pharmaceuticals
Attention: Paula J. Oliver
Senior Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Oliver:

Please refer to your supplemental new drug application dated October 14, 2002, received October 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium Advanced (loperimide hydrochloride and simethicone) Caplet.

This supplemental new drug application provides for labeling for the 2- caplet Imodium Advanced Pouch only.

We have completed our review of this application 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 labeling submitted October 14, 2002. Accordingly, the supplemental application is approved effective on the date of this letter.

We agree that the 2-caplet Imodium Advanced pouch meets the definition of a convenience size product currently covered by the partial delay of compliance dates for the labeling of OTC drug products (21 CFR 201.66).

We remind you that the delay in compliance dates for "convenience-size" packages remains in effect until a final rule issues with respect to the labeling of such OTC drug products or until such time as the agency issues further notice (67 FR 16304 at 16307).

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit the FPL electronically 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, in no case 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 21-140/S-002." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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 Dan Keravich, Regulatory Project Manager, at (301) 827-2248.

Sincerely,

{See appended electronic signature page}
Charles Ganley, M.D.
Division Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure (2)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Charles Ganley
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