DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-140/S-013

McNeil Consumer Healthcare
Attention: Hina S. Harlow, Pharm.D.
Associate Director, Global Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Dr. Harlow:

Please refer to your supplemental new drug application dated October 9, 2007, received October 10, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium Advanced (2 mg loperamide HCl and 125 mg simethicone) tablets.

This supplemental new drug application proposes revised labeling for the 2-count package size for the reformulated tablet approved on September 14, 2007.

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.

This 2-count pouch meets the definition of a convenience size product currently subject to the partial delay of compliance dates for the labeling of nonprescription drug products announced in the Federal Register (FR) on April 5, 2002. We remind you that this delay in compliance dates for convenience size packages remains in effect until a final rule issues with respect to the labeling of such nonprescription drug products or until such time as the agency issues further notice. See 67 FR 16304 at 16307.

The final printed labeling (FPL) must be identical to the enclosed 2-count single pouch labeling submitted October 9, 2007.

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 21-140/S-013**." 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

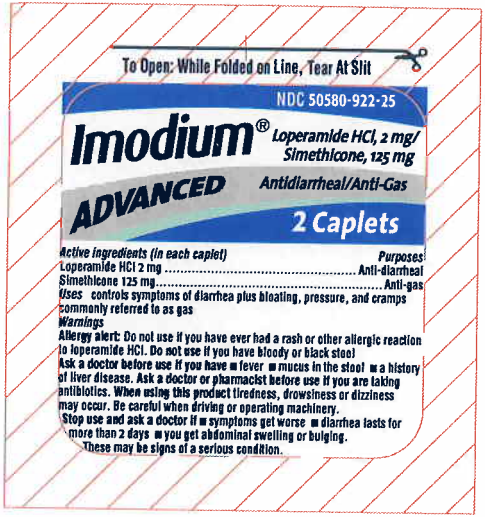
If you have any questions, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

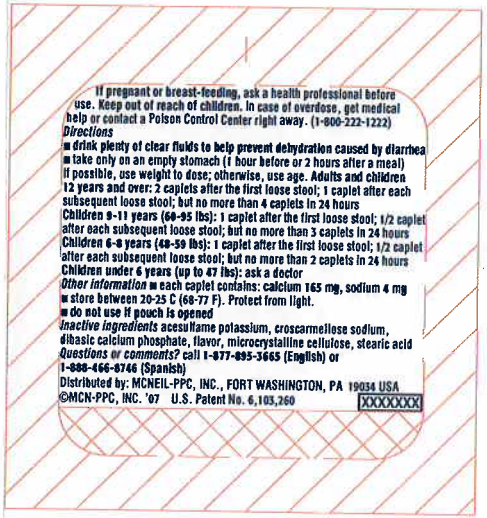
Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure


To Open: While Folded on Line, Tear At Slit
NDC 50580-922-25
Imodium®
Loperamide HCl, 2 mg/
Simethicone, 125 mg
ADVANCED
Antidiarrheal/Anti-Gas
2 Caplets
Active ingredients (in each caplet)
Purposes
Loperamide HCl 2 mg
Anti-diarrheal
Simethicone 125 mg
Anti-gas
Uses controls symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas
Warnings
Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl. Do not use if you have bloody or black stool
Ask a doctor before use if you have ■ fever ■ mucus in the stool ■ a history of liver disease. Ask a doctor or pharmacist before use if you are taking antibiotics. When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.
Stop use and ask a doctor if ■ symptoms get worse ■ diarrhea lasts for more than 2 days ■ you get abdominal swelling or bulging. These may be signs of a serious condition.


If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)
Directions
■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea
■ take only on an empty stomach (1 hour before or 2 hours after a meal)
If possible, use weight to dose; otherwise, use age. Adults and children 12 years and over: 2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
Children 9-11 years (60-95 lbs): 1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
Children 6-8 years (48-59 lbs): 1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
Children under 6 years (up to 47 lbs): ask a doctor
Other information ■ each caplet contains: calcium 165 mg, sodium 4 mg
■ store between 20-25 C (68-77 F). Protect from light.
■ do not use if pouch is opened
Inactive ingredients acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid
Questions or comments? call 1-877-895-3665 (English) or 1-888-466-8746 (Spanish)
Distributed by: MCNEIL-PPC, INC., FORT WASHINGTON, PA 19034 USA
©MCN-PPC, INC. '07 U.S. Patent No. 6,103,260
XXXXXXX

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

/s/

Joel Schiffenbauer

2/5/2008 02:24:22 PM