CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-140

APPROVAL LETTER

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-140

McNeil Consumer Healthcare
Attention: Jacqueline U. Linse
Associate Director, Regulatory Affairs
Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Linse:

Please refer to your new drug application (NDA) dated October 29, 1999, received November 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium Advanced Caplet (loperamide HCl and simethicone) Caplet.

We acknowledge receipt of your submissions dated January 10; May 4, 5, and 23; August 24 and 29; and November 16, 2000.

This new drug application provides for the use of Imodium Advanced (loperamide hydrochloride and simethicone) Caplet in controlling symptoms of diarrhea plus bloating, pressure, and cramps commonly referred to as gas.

We have completed the review of this 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. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted, and immediate container and carton labels submitted November 16, 2000) and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please 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 mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-140." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of

the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit two copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Over-the-Counter Drug Products and one copy to the Division of Gastrointestinal and Coagulation Drug Products. For administrative purposes, this submission should be sent to the NDA and should be identified as correspondence to approved NDA 21-140.

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

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products.

If you have any questions regarding this application, please contact Daniel Keravich, R.Ph., M.S., M.B.A., Project Manager, at (301) 827-2248.

Sincerely,

Charles Ganley, M.D.
Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research