CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-140

CORRESPONDENCE

Levine

NDA 21-140

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

SEP - 5 2000

Dear Ms. Linse:

We acknowledge receipt on August 30, 2000, of your August 29, 2000, amendment to your new drug application (NDA) 21-140, Imodium® Advanced (loperamide HCl 2mg and simethicone 125mg) Caplet.

We consider this a major amendment received by the Agency within three months of the FDA Modernization Act user fee due date. Therefore, the user fee clock is extended three months. The new due date is December 1, 2000.

If you have any questions, please contact Paul E. Levine, Jr., R.Ph., Project Manager, at (301) 827-7310.

Sincerely,

8-31-00

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

4 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

NOV 22 1999

NDA 21-140

McNeil Consumer Healthcare
Attention: Jacqueline U. Linse
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, PA 19034-2299

Dear Ms. Linse:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Imodium® Advanced Caplet
(loperamide HCl/simethicone tablets)

Therapeutic Classification: Standard (S)

Date of Application: October 29, 1999

Date of Receipt: November 1, 1999

Our Reference Number: NDA 21-140

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on December 31, 1999 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be September 1, 2000 and the secondary user fee goal date will be November 1, 2000.

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). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within 120 days of receipt of your pediatric drug development plan, we will notify you of the pediatric studies that are required under section 21 CFR 314.55.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with

the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov.cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will proceed with the pediatric drug development plan that you submit and notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857