CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-448

APPROVAL LETTER

NDA 20-448

JUL 24 1997

McNeil Consumer Products Company
Attention: Vivian Chester
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Chester:

Please refer to your new drug application dated March 14, 1994, received March 15, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium A-D (loperamide HCL) Chewable Tablets.

We acknowledge receipt of your submissions dated October 14, and November 26, 1996, and January 7, January 24, February 10, March 27, May 6, July 10 and July 18, 1997. The User Fee goal date for this application is July 27, 1997.

This new drug application provides for the control of the symptoms of diarrhea including Travelers' diarrhea.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on July 18, 1997. Accordingly, the application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional material 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 this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

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.

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, please contact Brian Strongin, Project Manager, at (301) 443-0483.

Sincerely yours,

LT 7-24-97

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

APPEARS THIS WAY ON ORIGINAL

cc:
Original NDA 20-448
HFD-180/Div. files
HFD-180/CSO/B.Strongin
HFD-180/E.Duffy
HFD-180/G.Chen
HFD-002/ORM (with labeling)
HFD-103/Office Director
HFD-101/L.Carter
HFD-820/ONDC Division Director
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFD-560/OTC (with labeling - for OTC Drug Products Only)
HFI-20/Press Office (with labeling)

Drafted by: BS/July 24, 1997/c:\wpfiles\n\20448707.0
Initialed by: LT/July 25, 1997
final: BS/July 25, 1997 B/7-24-97

APPROVAL (AP)

**APPEARS THIS WAY
ON ORIGINAL**

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-448

APPROVABLE LETTER

NDA 20-448

JUN 14 1996

McNeil Consumer Products Company
Attention: Vivian Chester
7050 Camp Hill Road
Fort Washington, PA 19034

Dear Ms. Chester:

Please refer to your March 14, 1994 new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imodium A-D (loperamide HCL) Chewable Tablets.

We acknowledge receipt of your amendments dated March 15, September 22, and December 21, 1995 and March 11 and March 21, 1996 submitted in response to our March 15, 1996 approvable letter.

We have completed the review of this application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit a satisfactory response to our letter dated June 14, 1996 requesting additional chemistry information.

In addition, it will be necessary for you to submit final printed labeling (FPL) identical in content to the enclosed marked-up draft labeling. Please submit sixteen copies of the final printed labeling, ten of which are individually mounted on heavy weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of that FPL may be required.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

Should you have any questions, please contact:

Brian Strongin
Consumer Safety Officer
Telephone: (301) 443-0483

Sincerely yours,

Stephen B. Fredd, M.D.
Director
Division of Gastrointestinal and Coagulation
Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Draft Labeling

**APPEARS THIS WAY
ON ORIGINAL**

cc:

Original NDA 20-448
HFD-180/Div. Files
HFD-2/M.Lumpkin
HFD-80
HFD-180/B.Strongin
HFD-180/E.Duffy
HFD-180/G.Chen
HFD-870/L.Kaus
HFD-870/R.Pradhan
HFD-103/P.Botstein
HFD-101/L.Carter
DISTRICT OFFICE
HFD-40/DDMAC (with draft labeling)
HFD-560/D.Bowen (with labeling - for OTC Drug Products Only)

drafted: BS/May 29, 1996/c:\wpfiles\n\20448605.1
r/d Initials: S.Fredd/June 14, 1996
Final: BS/June 14, 1996

6/14/96

APPROVABLE (AE)

6/14/96

**APPEARS THIS WAY
ON ORIGINAL**