CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 20802

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-802

JAN 14 1998

Bristol-Myers Products
Attention: Steven J. Knapp, R.Ph.
1350 Liberty Avenue
Hillside, New Jersey 07207-6050

Dear Mr. Knapp:

Please refer to your new drug application dated January 14, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Excedrin Migraine (acetaminophen, aspirin, and caffeine tablets) Tablets, Caplets, and Geltabs, 250 mg, 250 mg, and 65 mg.

We acknowledge receipt of your submissions dated February 18, 20, and 27, March 11, April 15(2), 16, 17, 25, and 30, May 15 and 20, June 3 and 13, August 22, September 30, October 10, November 18, 19, and 25, and December 2, 1997. The User Fee goal date for this application is January 15, 1998.

This new drug application provides for the temporary relief of mild to moderate pain associated with migraine headache for Over-the-Counter (OTC) use.

We have completed the review of this application, including the submitted draft labeling, 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 revised draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed revised draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 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 "FINAL PRINTED LABELING" for approved NDA 20-802. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit four copies of the introductory promotional material and also submit

any planned package insert 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 Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550, one copy to the Division of OTC Drug Products, HFD-560, and two copies of both the promotional material and any package insert to the Division of Drug Marketing, Advertising and Communications, HFD-40; all at the following address:

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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 Sandra N. Cook, Project Manager, at (301) 827-2090.

Sincerely,

JEH 1-14-98

John E. Hyde, Ph.D., M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic,
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

1-14-98 for

Debra L. Bowen, M.D.
Director
Division of Over-the-Counter
Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research

ENCLOSURE

cc:
Original NDA 20-802
HFD-550/Div. files
HFD-550/CSO/S.Cook CCK 1/14/98
HFD-550/Hyde
HFD-550/Mukherjee Am 12-11-97
HFD-550/Bhavnagri
HFD-725/Stat [illegible] 12/16/97
HFD-880/Bashaw EL 12-12-97
HFD-002/ORM (with labeling)
HFD-105/Office Director
HFD-101/L.Carter
HFD-830/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)
HFD-021/ACS (with labeling)

12/19/97

Concurrence:
Chem TL/Patel cgf for HP 12/15/97
Pharm TL/Chen CHC 12/11/97

Drafted by: S Cook/December 3, 1997/nda20802.ap

APPROVAL (AP)