CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-802/S002

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-802/S-002

DEC 29 1998

Bristol-Myers Products
1350 Liberty Avenue
Hillside, New Jersey 07207

Attention: Steven J. Knapp, Senior Director, Global Regulatory Affairs

Dear Mr. Knapp:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Excedrin®Migraine (acetaminophen, aspirin, caffeine tablets) Tablets, Caplets and Geltabs, 250mg, 250mg, and 65mg

NDA Number: 20-802

Supplement Number: S-002

Date of Supplement: December 18, 1998

Date of Receipt: December 18, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on February 16, 1998, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

Maria Rossana R. Cook, M.B.A.
Chief, Project Management Staff
Division of Over-the-Counter Drug Products, HFD-560
Office of Drug Evaluation V
Center for Drug Evaluation and Research