# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

## *APPLICATION NUMBER:*
# 21-317

***Trade Name:*** Bayer Extra Strength Aspirin for Migraine Pain Tablets 500 mg.

***Generic Name:*** acetylsalicylic acid

***Sponsor:*** Bayer Corporation, Consumer Care Division

***Approval Date:*** October 18, 2001

***Indications:*** Provides for the use of Bayer Extra Strength Aspirin for Migraine Pain form mild to moderate migraine pain.

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## CONTENTS

| | Included | Pending Completion | Not Prepared | Not Required |
|---|---|---|---|---|
| Approval Letter | X | | | |
| Tentative Approval Letter | | | | |
| Approvable Letter | | | | |
| Final Printed Labeling | X | | | |
| Medical Review(s) | X | | | |
| Chemistry Review(s) | X | | | |
| EA/FONSI | | | | |
| Pharmacology Review(s) | | | | |
| Statistical Review(s) | | | | |
| Microbiology Review(s) | | | | |
| Clinical Pharmacology Biopharmaceutics Review(s) | X | | | |
| Bioequivalence Review(s) | | | | |
| Administrative Document(s) | X | | | |
| Correspondence | X | | | |

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*APPLICATION NUMBER:*

**21-317**

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-317

Bayer Corporation, Consumer Care Division
Attention: Judy Doyle
Associate Director Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Dear Ms. Doyle:

Please refer to your new drug application (NDA) dated December 15, 2001, received December 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bayer Extra Strength Aspirin for Migraine Pain (acetylsalicylic acid) Tablets, 500 mg.

We acknowledge receipt of your submissions dated December 18, 2001, February 7, 2001, March 15 and 22, 2001, April 20 and 25, 2001, May 31, 2001 and October 9, and 17, 2001. We also acknowledge withdrawal of the proposed Midol Migraine labeling submitted separately on October 17, 2001.

This new drug application provides for the use of Bayer Extra Strength Aspirin for Migraine Pain (acetylsalicylic acid) Tablets, 500 mg, for mild to moderate migraine pain.

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 (Bayer Extra Strength Aspirin for Migraine Pain) 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 text provided in Bayer's labeling commitment letters dated October 9, 2001 and October 17, 2001 and must be formatted in accordance with the requirements of 21 CFR 201.66. The labeling for the approved "Drug Facts" format must be identical to the version provided by the Agency in the facsimile dated October 2, 2001, with the minor modification described in your letter dated October 9, 2001. 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 the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 "FPL for approved NDA 21-317." Approval of this submission by FDA is not required before the labeling is used.

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)(21 CFR 314.55 (or 601.27)). The Agency has not made a determination if a health benefit would be gained by studying Bayer Extra Strength Aspirin for Migraine Pain in pediatric patients for its approved indications. FDA is deferring submission of the pediatric assessments of safety and effectiveness that may be required under these regulations. FDA will inform you in the future whether pediatric studies are required under the rule. If FDA determines at that time that pediatric studies are necessary, FDA will also set a specific time at which you must submit the required assessments.

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

Division of OTC Drug Products, HFD-560
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 set forth under 21 CFR 314.80 and 314.81 for an approved NDA. To comply with these regulations, all 3-day and 15-day alert reports, periodic adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA for this drug product, not to this NDA. This includes the quarterly periodic adverse drug experience reports required by this new NDA. In the future, no submissions should be made to this NDA except for the final printed labeling, as requested above.

If you have any questions, contact Walter J. Ellenberg, Ph.D., Project Manager, at (301) 827-2222.

Sincerely,

*{See appended electronic signature page}*

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

*{See appended electronic signature page}*

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research