CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-317

CHEMISTRY REVIEW(S)

Division of Over the Counter Drug Products
HFD-560
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-317 **DATE REVIEWED:** 03-OCT-2001

REVIEW #: 1 **REVIEWER:** Rao Puttagunta

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL NDA	15-DEC-2000	19-DEC-2000	29-DEC-2000
Amendment1	29-JAN-2001	30-JAN-2001	09-FEB-2001
Amendment 2	10-AUG-2001	14-AUG-2001	20-AUG-2001
Amendment 3	13-SEP-2001	14-SEP-2001	28-SEP-2001
Amendment 4	24-SEP-2001	25-SEP-2001	28-SEP-2001
Amendment 5	25-SEP-2001	26-SEP-2001	01-OCT-2001
Amendment 6 (Fax)	02-OCT-2001		

NAME & ADDRESS OF APPLICANT:

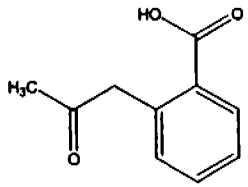
Bayer Corporation, Consumer Care Division
36 Columbia Road
Morristown, NJ 07962
Phone: 973-408-8181 (Judy Doyle, Assoc. Dir., Regulatory Affairs)

DRUG PRODUCT NAME

Proprietary:	Bayer Migraine
Established:	Aspirin
Code Name/#:	N/A
Chem.Type/Ther.Class:	5S

PHARMACOL. CATEGORY: Analgesic (Migraine)
DOSAGE FORM: Tablet (Caplet)
STRENGTHS: 500 mg
ROUTE OF ADMINISTRATION: Oral
DISPENSED: ___ Rx _X_ OTC
SPECIAL PRODCUTS ___Yes _X_ No

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:



Chemical Name: 2-(acetyloxy)-benzoic acid
Molecular Formula: $C_9H_8O_4$ **Molecular Weight:** 180.16

SUPPORTING DOCUMENTS:

DMF Type/#	Holder	Item/Component	Review Date	Status	LOA
[redacted]			8/31/01	Adequate	11/30/00
			11/15/00	Adequate	10/23/00
			8/30/01	Adequate	12/07/00
			8/30/01	Adequate	11/29/00
			2/09/01	Adequate	8/23/00
			Comply with 21 CFR §177.1520 & 178.2010	Adequate Adequate	10/12/00 11/30/00
			2/09/01	Adequate	11/20/00
			2/09/01	Adequate	11/03/00
			Complies with 21 CFR §177.1520, 178.2010 & 178.3297	Adequate	11/03/00
			3/24/01	Adequate	10/12/00
			Complies with 21 CFR §177.1520 & 178.2010	Adequate	11/20/00
			2/23/01	Adequate	11/08/00
			12/29/00	Adequate	11/01/00
			5/11/99	Adequate	11/02/00
			3/20/01	Adequate	9/11/00

RELATED DOCUMENTS: IND [redacted]

CONSULTS/REQUESTS:

Request Type	Date Requested	Status
EER	2/15/01	OC Recommendation – Acceptable (See attached EER Summary Report)
Method Validation	N/A	USP method
OPDRA	N/A	N/A

Amendments

Date	Description
1/29/01	Pre Approval Inspection readiness statement
8/10/01	Stability data for additional container sizes, stability data update and revised in-process acceptance criteria for the tablet hardness
9/13/01	Method validation package
9/24/01	To include the USP method as the regulatory method and retain the proposed analytical method as an alternate method
9/25/01	Correction of the analytical method number
10/02/01	Clarification regarding an apparent lack of correlation between unit dose and batch amounts

REMARKS:

Drug Substance: This NDA does not contain information about thedrug substance. The applicant references [redacted] for Aspirin USP.

[redacted] were reviewed and found adequate.

Drug Product: The complete CMC information is provided. The stability data include 6 months accelerated ([redacted]) and 18 months long-term [redacted] results in the 90 cc HDPE bottle from the proposed container supplier. The submission also contains 6 months accelerated ([redacted]) and 36 months long-term [redacted] results in HDPE bottle from different source other than the proposed container supplier. Proposed expiration period is 24 months.

The following DMFs were reviewed and found adequate:

[redacted]

APPEARS THIS WAY
ON ORIGINAL

CONCLUSIONS & RECOMMENDATIONS:

The information provided on the chemistry, manufacture and controls of the drug substance and drug product is adequate. The DMFs for the active ingredients were reviewed and found adequate.

Recommendation(s): Form the chemistry standpoint, this NDA is recommended for approval.

cc:
Orig. NDA# 21-317
HFD-550/Division File
HFD-550/Chem./R.Puttagunta
HFD-550/T.L./JSmith
HFD-560/CSO/W.Ellenberg
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