CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-920

CHEMISTRY REVIEW(S)

NDA 21-920

Naproxen Sodium Capsules

Banner Pharmacaps Inc.

Rao Puttagunta, Ph.D.
Branch III/Pre-Marketing Assessment Division II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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Chemistry Review Data Sheet

1. NDA #: 21-920

2. REVIEW #: 1

3. REVIEW DATE: 12-JAN-2006

4. REVIEWER: Rao Puttagunta, Ph.D.

5. PREVIOUS DOCUMENTS: N/A

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original	15-APR-2005
Amendment (BC)	29-JUL-2005
Amendment (BC)	14-OCT-2005
Amendment (BC)	04-JAN-2006
Amendment (BC)	05-JAN-2006

7. NAME & ADDRESS OF APPLICANT:

Name:	Banner Pharmacaps Inc.
Address:	4125 Premier Drive High Point, NC 27265
Representative:	Shelly K. Meachum Director, Regulatory Affairs
Telephone:	336-812-8700 x 3312

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: N/A
b) Non-Proprietary Name (USAN): Naproxen Sodium Capsules
c) Code Name/# (ONDC only): N/A
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 3
- Submission Priority: S

Chemistry Review Data Sheet

9. LEGAL BASIS FOR SUBMISSION: 505 (b)(2)
RLD: Aleve® (naproxen sodium) Tablets , 220 mg, Bayer Healthcare, NDA 20-204

10. PHARMACOL. CATEGORY: Analgesic, Anti-inflammatory and Anti-pyretic

11. DOSAGE FORM: Capsule, Liquid Filled

12. STRENGTH/POTENCY: 220 mg (naproxen sodium)/capsule

13. ROUTE OF ADMINISTRATION: Oral

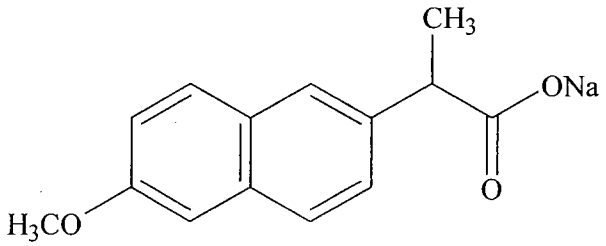
14. Rx/OTC DISPENSED: ___Rx __X_OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

_____SPOTS product – Form Completed

___X___Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:



(-)-6-methoxy-α-methyl-2-naphthaleneacetic acid, sodium salt, $C_{14}H_{13}NaO_3$, Mol. Wt. 252.24

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17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
11940	II	Albemarle Corp.	Naproxen Sodium	3	Adequate	---	---
14194	IV	Banner Pharmacaps	Gel Mass	3	Adequate	---	---
				4	N/A	---	Complies with 21 CFR §177.1520
				4	N/A	---	Complies with 21 CFR §177.1520
				4	N/A	---	Complies with 21 CFR §177.1210
				4	N/A	---	Complies with 21 CFR §177.1520
				4	N/A	---	Complies with 21 CFR §177.1520
				4	N/A	---	Complies with 21 CFR §177.1520, 178.2010 & 178.3297
				4	N/A	---	Complies with 21 CFR §177.1520

DMFs continued:

[1] Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:
2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: N/A

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND	71,161	Naproxen sodium capsules, 220 mg

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A		
EES	Acceptable	6/28/05	J. D Ambrogio
Pharm/Tox	N/A		
Biopharm	N/A		
LNC	N/A		
Methods Validation	N/A per new ONDC policy		
OPDRA	N/A		
EA	Categorical Exclusion		
Microbiology	N/A		

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The Chemistry Review for NDA 21-920

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From the chemistry standpoint this NDA is recommended for approval.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

N/A

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

1. Drug Substance

Naproxen sodium is manufactured by Albemarle Corporation, Orangeburg, SC. The CMC information naproxen sodium was referenced to DMF 11940. The DMF has been recently reviewed and found to be adequate.

2. Drug Product:

The Naproxen sodium capsules contain 220 mg of naproxen sodium (200 mg of naproxen) per capsule. These liquid filled dark green soft gelatin capsules contain naproxen sodium solubilized in a medium containing polyethylene glycol, propylene glycol, lactic acid, and povidone. The reference listed drug Aleve® tablets contain 220 mg of naproxen sodium.

The drug product is packaged in —— bottles with a child-resistant cap.

B. Description of How the Drug Product is Intended to be Used

The naproxen sodium capsules are orally administered for temporary relief of minor aches and pains due to: headache, backache, muscular aches, common cold, minor pain of arthritis, toothache, and menstrual cramps; and temporary reduction of fever. The naproxen sodium capsules are supplied in bottles of 15 and 200 counts. Each capsule contains naproxen sodium 220 mg (equivalent of naproxen 200 mg). The recommended dosing schedule is 1 capsule every 8 to 12 hours and the maximum daily dose is 3 capsules.

Recommended storage conditions: 20-25°C (68-77°F).

The submitted drug product stability data include 18 months of stability data at 25°C/60%RH and for 12 months at 30°C/65%RH. The applicant proposed an expiration dating period of 24 months.

C. Basis for Approvability or Not-Approval Recommendation

The CMC information of the drug substance naproxen sodium was referenced to the DMF 11940. This DMF has been recently reviewed and found to be adequate. Since the drug substance is a compendial item it is tested according to the USP specification and some additional tests such as residual solvents.

All ingredients in the drug product are of USP/NF grade except for the sorbitol ——— solution. The composition of the drug product is not a safety concern.

Appropriate in-process, release and stability acceptance criteria have been established for the drug product to ensure consistency in quality. The packaging materials were found adequate. The drug product specification was considered adequate.

The submitted drug product stability data for 18 months conform to the established acceptance criteria. The submitted stability data and the statistical analysis were considered adequate to support the proposed 24-month expiration dating period.

The proposed dissolution acceptance criterion of Q = ——— in 45 minutes is acceptable.

The NDA 21-920 is recommended for approval based on the submitted CMC information.

III. Administrative

A. Reviewer's Signature

N/A

B. Endorsement Block

N/A

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C. CC Block

N/A

22 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Chemistry- A

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/s/

Rao Puttagunta
2/16/2006 07:49:27 AM
CHEMIST

Moo-Jhong Rhee
2/16/2006 09:09:46 AM
CHEMIST
Chief, Branch III

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