

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022372Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

April 7, 2009

NDA: 22-372

Drug Product Name

Proprietary: SUPREP

Non-proprietary: Sodium sulfate, potassium sulfate & magnesium sulfate for oral solution

Review Number: 1

Dates of Submission(s) Covered by this Review

<u>Letter</u>	<u>Stamp</u>	<u>Review Request</u>	<u>Assigned to Reviewer</u>
July 1, 2008	July 2, 2008	September 19, 2008	September 24, 2008

Submission History (for amendments only) – N/A

Applicant/Sponsor

Name: Braintree Laboratories, Inc.

Address: 60 Columbian Street West, Braintree, MA 02185

Representative: Vivian Caballero - Director, Regulatory Affairs

Telephone: 781-843-2202, Fax: 781-843-7932

Name of Reviewer: Vinayak. B. Pawar, Ph.D.

Conclusion: The NDA is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** Gastrointestinal preparation solution.
3. **MANUFACTURING SITE:** Braintree Laboratories, Braintree, MA
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Two 6 oz bottles per dose, orally administered. The product is supplied as a liquid concentrate in two 6 ounce bottles. Along with it is a mixing cup which is used for constituting and diluting the product with water prior to drinking. A dilution to 16 ounces is required, with instructions to drink the solution [REDACTED] (b) (4).
5. **METHOD(S) OF STERILIZATION:** [REDACTED] (b) (4)
6. **PHARMACOLOGICAL CATEGORY:** A bowel prep kit for cleansing of the colon as a preparation for colonoscopy in adults.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** The consult request review of an Original NDA 22-372 for SUPREP, an oral gastrointestinal solution. SUPREP® BOWEL PREP KIT (sodium sulfate, potassium sulfate and magnesium sulfate for oral solution) is intended for bowel cleansing prior to colonoscopy. The product [REDACTED] (b) (4) Sodium Benzoate, NF [REDACTED] (b) (4). An IQA was filed by Marie Kowblansky on August 25, 2008.

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – Recommended for approval.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The oral drug product is (b) (4) filled in bottles in a controlled environment as shown in section 2.3.P.3.
- B. Brief Description of Microbiology Deficiencies** - None
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Vinayak B. Pawar, Ph.D.
Reviewer, CDER/OPS/NDMS
- B. Endorsement Block** _____
David Hussong, Ph.D.
Assoc. Director., CDER/OPS/NDMS
- C. CC Block**
NA

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immediately following this page.

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Vinayak Pawar
4/7/2009 02:59:11 PM
MICROBIOLOGIST

The NDA 22-372 is recommended for approval from microbiology
product quality standpoint.

James McVey
4/7/2009 03:13:01 PM
MICROBIOLOGIST
I concur.