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 & magnesiu sulfate for oral solution

Review Number: 1

Dates of Submission(s) Covered by this Review

<table>
<thead>
<tr>
<th>Letter Stamp</th>
<th>Review Request</th>
<th>Assigned to Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 1, 2008</td>
<td>July 2, 2008</td>
<td>September 19, 2008</td>
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<td></td>
<td>September 24, 2008</td>
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</table>

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.

5. **METHOD(S) OF STERILIZATION:**

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 Sodium Benzoate, NF. An IQA was filed by Marie Kowblansky on August 25, 2008.
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 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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/s/
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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.