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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

19-386/S-021

Microbiology Review(s)

Product Quality Microbiology Review
Consult review for HFD-110

22 JANUARY 2003

ANDA/NDA:	NDA 19-386/SCF021
Name of Drug:	BREVIBLOC
Review Number:	1
Submission Date:	October 24, 2002
Applicant:	Baxter Health Corporation
Name of Reviewer:	Vinayak Pawar
Conclusion:	The application is recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **NDA/ANDA/IND/:** NDA 19-386/SCF021

2. **REVIEW NUMBER:** 1

3. **REVIEW DATE:** 22, January 2003

4. **TYPE OF SUPPLEMENT:** SCF

5. **SUPPLEMENT PROVIDES FOR:** a new formulation with reduced overage of active ingredients and [redacted] in place of [redacted]

6. **APPLICANT/SPONSOR:**

Name: Baxter Healthcare Corporation
Representative: Priya Jambhekar
Telephone: (908)-286-7215

7. **MANUFACTURING SITE:** Faulding Puerto Rico Inc., Aguadilla, PR 00604

8. **DRUG PRODUCT NAME:**
Proprietary: Brevibloc
Non-proprietary: esmolol HCL in sodium chloride
Drug Priority Classification: Standard

9. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Injectable, 10 mg/mL in 10 mL ready to use vials

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

11. **PHARMACOLOGICAL CATEGORY:**

B. 1. **DOCUMENT/LETTER DATE:** October 24, 2002
2. **RECEIPT DATE:** October 25, 2002
3. **CONSULT DATE:** December 18, 2002
4. **DATE OF AMENDMENTS:** NA
5. **ASSIGNED FOR REVIEW:** January 7, 2003
6. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** The consult requests review of NDA 19-386/SCF021 for a new formulation with reduced overage of active ingredients and [redacted] vials in place of the current [redacted] Volumes 3 and

4 of 5 volumes were submitted for review. There are no changes in manufacturing process or the manufacturing controls.

Executive Summary

I. Recommendations

A. Recommendation on Approvability -
The proposal to change the currently used — method for — of the product to — adequately assures the safety of the product Brevibloc®. The proposal is recommended for approval from microbiological standpoint.

B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable
NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology
The changes made to the product formulation for reducing overage of active ingredients and addition of an isotonic agent sodium chloride to the product do not affect the manufacturing process. However, the — method has been changed from — The manufacturing controls other than — remain unchanged.

B. Brief Description of Microbiology Deficiencies
None

C. Assessment of Risk Due to Microbiology Deficiencies-
NA

III. Administrative

A. Reviewer's Signature /S/

B. Endorsement Block
Vinayak Pawar/22, January 2003
Peter H. Cooney/

C. CC Block
cc:
Original NDA 19-386
HFD-110/Division File/Melissa Robb

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