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RESEARCH**

APPLICATION NUMBER:

22-102

MICROBIOLOGY REVIEW(S)

12/5/06

Product Quality Microbiology Review

Review for Division of Metabolism and Endocrinology Products

28 November 2006

NDA: 22-102

Drug Product Name

Proprietary: _____ Nasal Spray

Non-proprietary: cyanocobalamin, USP

Drug Product Priority Classification: S1

b(4)

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
September 26, 2006	Electronic submission	November 13, 2006	November 14, 2006

Submission History (for amendments only)-NA

Applicant/Sponsor

Name: Fleming and Company, Pharmaceuticals
Address: 1733 Gilsinn Lane, Fenton, MO 63026
Representative: Phillip W. Dritsas, President
Telephone: 636-343-5306, x333

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

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

Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUBMISSION: Original submission
2. SUBMISSION PROVIDES FOR: NA
3. MANUFACTURING SITE: Fleming & Company,
Pharmaceuticals, Fenton, MO
4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
STRENGTH/POTENCY: Mutidose, nonsterile nasal spray
solution of 0.25 mg/mL cyanocobalamin.
5. METHOD(S) OF STERILIZATION: _____ **b(4)**
6. PHARMACOLOGICAL CATEGORY: _____ **b(4)**
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: The consult requests review of NDA 22-102 for _____ **b(4)**
drug product. This document was submitted in an electronic format. The product
is a non-sterile solution of cyanocobalamin indicated for . _____ **b(4)**
_____ The solution is preserved in Benzyl
Alcohol and Benzalkonium Chloride.

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APPEARS THIS WAY ON ORIGINAL

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – Based on the microbiology product quality review, the application is recommended for approval.
- B. **Recommendations 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 –**

b(4)

- B. **Brief Description of Microbiology Deficiencies - None**
- C. **Assessment of Risk Due to Microbiology Deficiencies – Minimal risk assessed.**

III. Administrative

- A. **Reviewer's Signature** _____
Vinayak B. Pawar, Ph.D.
- B. **Endorsement Block** _____
Bryan Riley, Ph.D.
- C. **CC Block**
N/A

5 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Vinayak Pawar
12/4/2006 03:22:11 PM
MICROBIOLOGIST

Recommended for approval from microbiology product quality standpoint.

Bryan Riley
12/5/2006 09:02:36 AM
MICROBIOLOGIST