CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-646

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-510
25 August 2003

NDA: 21-646 BI

Drug Product Name
Proprietary: Infuvite® Pediatric
Non-proprietary: vitamins for infusion
Drug Product Classification: Pharmacy Bulk Package

Review Number: 1

Subject of this Review
Submission Date: 16 July 2003
Receipt Date: 18 July 2003
Consult Date: 30 July 2003
Date Assigned for Review: 20 August 2003

Submission History (for amendments only)
Date(s) of Previous Submission(s): 31 March 2003
Date(s) of Previous Micro Review(s): 10 June 2003

Applicant/Sponsor
Name: Sabex Pharmaceutical Products
Address: 145 Jules-Leger, Boucherville, QC, Canada
Representative: Leonor Ferreira
Telephone: (450)641-4903 ext. 2161

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of sterility assurance.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Prior Approval

2. **SUPPLEMENT PROVIDES FOR:** Addition of a pharmacy bulk package.

3. **MANUFACTURING SITES:** Boucherville (Quebec), Canada

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Intravenous

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** The product is indicated as a daily multivitamin maintenance supplement for infants and children aged to 11 years of age receiving parenteral nutrition.

B. **SUPPORTING/RELATED DOCUMENTS:** NDA 21-163, NDA 21-265, DMF [redacted]

REMARKS: The supplement references NDA 21-163 for Infuvite Adult which was approved 18 May 2000 and NDA 21-265 for Infuvite Pediatric which was approved 21 February 2001.

Future batches are to be produced using [redacted] in a [redacted] This [redacted] is to be the subject of an amendment filed as soon as validation data are available.

The [redacted] used in production of the pilot batches for Vial #1 of the pediatric pharmacy bulk package was [redacted] located in [redacted] and capped using Vial [redacted] #1. The proposed [redacted] for Vial #2 of the pharmacy bulk package are [redacted]. The submission contains only validation descriptions and data for these [redacted]. Therefore, only these [redacted] should be used for [redacted] product until the amendment for the [redacted] is approved.

filename: n21646r2.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval on the basis of sterility assurance of the drug product.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology - ———

B. Brief Description of Microbiology Deficiencies – none

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
P. Stinavage
P.H. Cooney

C. CC Block
cc:
Original NDA 21-646
HFD-510/Division File/NDA 21-646/E. Galliers/D. Lewis

1 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Microbiology-_____

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

/s/

Paul Stinavage
9/24/03 10:29:49 AM
MICROBIOLOGIST
Response to deficiencies

Peter Cooney
9/24/03 11:05:10 AM
MICROBIOLOGIST

Product Quality Microbiology Review
Review for HFD-510
10 June 2003

NDA: 21-646

Drug Product Name
Proprietary: Infuvite® Pediatric
Non-proprietary: vitamins for infusion
Drug Product Classification: Pharmacy Bulk Package

Review Number: 1

Subject of this Review
Submission Date: 31 March 2003
Receipt Date: 01 April 2003
Consult Date: 10 April 2003
Date Assigned for Review: 05 May 2003

Applicant/Sponsor
Name: Sabex Pharmaceutical Products
Address: 145 Jules-Leger, Boucherville, QC, Canada
Representative: Leonor Ferreira
Telephone: (450)641-4903 ext. 2161

Name of Reviewer: Paul Stinavage

Conclusion: The application is approvable pending resolution of Product Quality Microbiology concerns.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Prior Approval

2. **SUPPLEMENT PROVIDES FOR:** Addition of a pharmacy bulk package.

3. **MANUFACTURING SITES:** Boucherville (Quebec), Canada

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Intravenous

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** The product is indicated as a daily multivitamin maintenance supplement for infants and children aged to 11 years of age receiving parenteral nutrition.

B. **SUPPORTING/RELATED DOCUMENTS:** NDA 21-163, NDA 21-265, DMF [redacted]

C. **REMARKS:** The product will be manufactured by:

Sabex
145 Jules-Leger Street
Boucherville, QC, Canada
J4B7K8

The supplement references NDA 21-163 for Infuvite Adult which was approved 18 May 2000 and NDA 21-265 for Infuvite Pediatric which was approved 21 February 2001.

Future batches are to be produced using [redacted] This [redacted] is to be the subject of an amendment filed as soon as validation data are available.

The [redacted] used in production of the pilot batches for Vial #1 of the pediatric pharmacy bulk package was [redacted] located in [redacted] using Vial [redacted] #1. The proposed [redacted] Vial #2 of the pharmacy bulk package are [redacted]. The submission contains only validation descriptions and data for these [redacted]. Therefore, only these [redacted] should be used for [redacted] product until the amendment for the [redacted] is approved.

filename: n21646.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is approvable pending resolution of Product Quality Microbiology concerns.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – [redacted]

B. Brief Description of Microbiology Deficiencies – none

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
P. Stinavage
P.H. Cooney

C. CC Block
cc:
Original NDA 21-163
HFD-510/Division File/NDA 21-163/E. Galliers/D. Lewis

2 Page(s) Withheld

2 § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Microbiology-_____

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

/s/

Paul Stinavage
6/13/03 04:53:54 AM
MICROBIOLOGIST
Pharmacy bulk package of approved product.

Peter Cooney
6/13/03 09:15:32 AM
MICROBIOLOGIST