CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-365

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
15 July 2002
Review for HFD-120

NDA:	**21-365**
Drug Product Name	
Proprietary:	Lexapro
Non-proprietary:	Escitalopram Oxalate
Drug Product Classification:	3S
Review Number:	1
Subject of this Review	
Submission Date:	November 2, 2001
Receipt Date:	March 7, 2002
Consult Date:	March 8, 2002
Date Assigned for Review:	March 19, 2002
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	
Date(s) of Previous Micro Review(s):	
Applicant/Sponsor	
Name:	Forest Laboratories
Address:	Harborside Financial Center Plaza Three, Suite 602 Jersey City, NJ 07311
Representative:	Esin Kosal
Telephone:	(201) 386-2126
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Approvable pending resolution of microbiological deficiencies

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Original NDA submission

2. **SUPPLEMENT PROVIDES FOR:** N/A

3. **MANUFACTURING SITE:** Forest Pharmaceuticals, Inc.
Manufacturing Plant One
3721 Laclede Avenue
St. Louis, MO.

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

- Solution
- 5 mg/5 mL
- Oral

5. **METHOD(S) OF STERILIZATION:** Non-sterile drug product

6. **PHARMACOLOGICAL CATEGORY:** Treatment of depression

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** This is a non-sterile drug product preserved with methylparaben and propylparaben. John Baiano of Forest Laboratories was contacted on July 8, 2002. He informed me that preservative effectiveness testing had not been done yet. He will send me the results once the tests are completed.

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APPEARS THIS WAY
ON ORIGINAL

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 21-365 is approvable pending the resolution of microbiology deficiencies.

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 -

Lexapro is a non-sterile liquid oral dosage form preserved with methylparaben and propylparaben. Microbial limits testing and preservative testing are conducted upon release and as part of the stability schedule.

B. Brief Description of Microbiology Deficiencies -

The results of preservative effectiveness testing were not provided.

C. Assessment of Risk Due to Microbiology Deficiencies -

Preservative effectiveness should be demonstrated as insurance against the growth of potentially harmful microorganisms in the drug product.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

In DFS

C. CC Block

In DFS

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/s/

Stephen Langille
7/15/02 02:34:05 PM
MICROBIOLOGIST

Peter Cooney
7/15/02 03:35:30 PM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL

Product Quality Microbiology Review

5 Sept. 2002

Review for HFD-120

NDA:	**21-365-BC**
Drug Product Name	
Proprietary:	Lexapro
Non-proprietary:	Escitalopram Oxalate
Drug Product Classification:	3S
Review Number:	2
Subject of this Review	
Submission Date:	August 19, 2002
Receipt Date:	August 20, 2002
Consult Date:	August 29, 2002
Date Assigned for Review:	August 29, 2002
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	November 2, 2001
Date(s) of Previous Micro Review(s):	July 15, 2002
Applicant/Sponsor	
Name:	Forest Laboratories
Address:	Harborside Financial Center Plaza Three, Suite 602 Jersey City, NJ 07311
Representative:	John Baiano
Telephone:	(201) 386-2126
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUPPLEMENT:** Amendment to original submission

2. **SUPPLEMENT PROVIDES FOR:** Antimicrobial effectiveness testing

3. **MANUFACTURING SITE:** Forest Pharmaceuticals, Inc.
Manufacturing Plant One
3721 Laclede Avenue
St. Louis, MO.

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Solution
- 5 mg/5 mL
- Oral

5. **METHOD(S) OF STERILIZATION:** Non-sterile drug product

6. **PHARMACOLOGICAL CATEGORY:** Treatment of depression

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** This is a non-sterile drug product preserved with methylparaben and propylparaben. John Baiano of Forest Laboratories was contacted on July 8, 2002. He informed me that preservative effectiveness testing had not yet been completed. NDA 21-365-BC was submitted on August 19, 2002 to provide the preservative test results for the stability batches.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -
NDA 21-365 is recommended for approval from the standpoint of microbial product quality.

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 -
Lexapro is a non-sterile liquid oral dosage form preserved with methylparaben and propylparaben. Microbial limits testing and preservative testing are conducted upon release and as part of the stability schedule.

B. Brief Description of Microbiology Deficiencies -
Not deficiencies were identified based upon the information provided

C. Assessment of Risk Due to Microbiology Deficiencies -
Not applicable

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block
In DFS

C. CC Block
In DFS

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/s/

Stephen Langille
9/19/02 08:51:54 AM
MICROBIOLOGIST

Peter Cooney
9/19/02 11:05:09 AM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL

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