CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-483

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD 120

16-October-2003

NDA:	21-483-AZ
Drug Product Name:	
Proprietary	GEODON® Oral suspension
Non-proprietary	ziprasidone HCL
Drug Product Classification:	
Review Number:	2
Subject of this Review	
Submission Date:	September 29, 2003
Receipt Date:	September 30, 2003
Consult Date:	October 13, 2003
Date Assigned for Review:	October 16, 2003
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	September 26, 2002
Date(s) of Previous Micro Review(s):	July 15, 2003
Applicant/Sponsor	
Name:	Pfizer Global Research and Development
Address:	Worldwide Regulatory Affairs 50 Pequot Avenue New London, CT 06320
Representative:	Brian A. Green
Telephone:	(860) 732-0959
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUPPLEMENT: NDA ammendment

2. SUPPLEMENT PROVIDES FOR: Not Applicable

3. MANUFACTURING SITE: Pfizer Inc.
400 W. Lincoln Avenue
Lititz, PA 17543

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

- Oral Suspension
- 10 mg/mL

5. METHOD(S) OF STERILIZATION: Non-sterile Drug Product

6. PHARMACOLOGICAL CATEGORY: Treatment of schizophrenia

B. SUPPORTING/RELATED DOCUMENTS: None

C. REMARKS: GEODON is a non-sterile aqueous drug product. Most of the CMC information for this application was provided in volumes 1.2 and 1.3. The first review of this submission was completed on July 15, 2003. The action letter was issued to the Applicant on July 18, 2003.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 21-483 is recommended for approval from the standpoint of product quality microbiology.

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

Not applicable

II. Summary of Microbiology Assessments

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

GEODON is a non-sterile aqueous oral drug product. The manufacturing process should limit the number and types of microorganisms present in the finished drug product. A suitable preservative must be added to the drug product in order to control microbial growth over the shelf life of the product.

B. Brief Description of Microbiology Deficiencies -

No 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

Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block

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/s/

Stephen Langille
11/6/03 11:26:39 AM
MICROBIOLOGIST

Peter Cooney
11/6/03 01:41:06 PM
MICROBIOLOGIST

Product Quality Microbiology Review
Review for HFD 120

15-July-2003

NDA:	21-483
Drug Product Name:	
Proprietary	GEODON® Oral suspension
Non-proprietary	ziprasidone HCL
Drug Product Classification:	
Review Number:	1
Subject of this Review	
Submission Date:	September 26, 2002
Receipt Date:	September 27, 2002
Consult Date:	April 4, 2003
Date Assigned for Review:	July 7, 2003
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	
Date(s) of Previous Micro Review(s):	
Applicant/Sponsor	
Name:	Pfizer Global Research and Development
Address:	Worldwide Regulatory Affairs 50 Pequot Avenue New London, CT 06320
Representative:	Brian A. Green
Telephone:	(860) 732-0959
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Approvable pending revision

Product Quality Microbiology Data Sheet

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

2. **SUPPLEMENT PROVIDES FOR:** Not Applicable

3. **MANUFACTURING SITE:** Pfizer Inc.
400 W. Lincoln Avenue
Lititz, PA 17543

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

- Oral Suspension
- 10 mg/mL

5. **METHOD(S) OF STERILIZATION:** Non-sterile Drug Product

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

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

C. **REMARKS:** GEODON is a non-sterile aqueous drug product. Most of the CMC information for this application was provided in volumes 1.2 and 1.3.

filename: c:\reviews\21-483r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 21-483 is approvable pending the revision of product quality microbiology issues.

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

Not applicable

II. Summary of Microbiology Assessments

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

GEODON is a non-sterile aqueous oral drug product. The manufacturing process should limit the number and types of microorganisms present in the finished drug product. A suitable preservative must be added to the drug product in order to control microbial growth over the shelf life of the product.

B. Brief Description of Microbiology Deficiencies -

The Applicant has failed to

- Provide adequate information regarding the manufacturing facility and methods to limit microbial contamination of the drug product
- Establish adequate microbial limits for GEODON
- Commit to frequent microbial limits testing
- Provide preservative effectiveness data

C. Assessment of Risk Due to Microbiology Deficiencies -

Failure to control the microbial population and preservative effectiveness of an aqueous non-sterile drug product could result in unacceptable levels of microbial contamination either at release or during the shelf life of the product.

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block

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/s/

Stephen Langille
7/15/03 01:43:53 PM
MICROBIOLOGIST

Peter Cooney
7/16/03 03:26:30 PM
MICROBIOLOGIST