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RESEARCH**

*APPLICATION NUMBER:*  
**022501Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

December 22, 2009

**NDA:** 22-501 Amendment

**Drug Product Name**  
**Proprietary:**

(b) (4)

**Non-proprietary:** Norethindrone acetate & Ethinyl estradiol tablets  
Ethinyl estradiol tablets &  
Ferrous fumarate tablets

**Review Number:** 2

## Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
December 17, 2009	December 17, 2009	December 18, 2009	December 18, 2009

## Submission History (for amendments only)

Submit Date(s)	Microbiology Review #	Review Date(s)
March 26, 2009	1	November 20, 2009

## Applicant/Sponsor

**Name:** Warner Chilcott Company, Inc.  
**Address:** 100 Enterprise Drive, Roackaway, NJ 07866  
**Representative:** Alvin Howard, Sr. Vice President, RA  
**Telephone:** 973-442-3233

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

**Conclusion:** The amended original NDA is recommended for approval from Product Quality Microbiology standpoint.

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## Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Amended original NDA
2. **SUBMISSION PROVIDES FOR:** An agreement to add Microbial Limits test criteria to the drug product specification.
3. **MANUFACTURING SITE:** Warner Chilcott Co. Inc., Fajardo, PR 00738
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Oral Tablets in 1mg NA, 10 mcg EE and 10 mcg EE.
5. **METHOD(S) OF STERILIZATION:** Non-sterile product.
6. **PHARMACOLOGICAL CATEGORY:** Prevention of pregnancy.
- B. **SUPPORTING/RELATED DOCUMENTS:** None.
- C. **REMARKS:** The consult requests review of NDA 22-501 an oral drug product (b) (4) (Norethindrone acetate & Ethinyl estradiol tablets, Ethinyl estradiol tablets & Ferrous fumarate tablets) for product quality microbiology review. The applicant proposed no microbial testing for the oral tablets. This resulted in a deficiency which was conveyed to Warner Chilcott and the sponsor was given the opportunity to discuss this deficiency in teleconference with the reviewer. In the teleconference held on December 14, 2009 Warner Chilcott agreed to amend the application to include the Microbial Limits test in their product specification.

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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability** – The amended original NDA is recommended for approval.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

### **II. Summary of Microbiology Assessments**

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – WC3016 1/10 tablets are made

(b) (4)

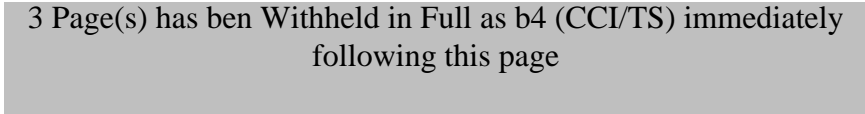


- B. Brief Description of Microbiology Deficiencies** – None
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A.

### **III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
**Vinayak B. Pawar, Ph.D.**
- B. Endorsement Block** \_\_\_\_\_  
**Stephen E. Langille, Ph.D.**
- C. CC Block**  
N/A

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WARNER  
CHILCOTT CO INC

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/s/  
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VINAYAK B PAWAR  
12/23/2009

STEPHEN E LANGILLE  
12/23/2009

# Product Quality Microbiology Review

November 20, 2009

**NDA:** 22-501

**Drug Product Name**  
**Proprietary:**

(b) (4)

**Non-proprietary:** Norethindrone acetate & Ethinyl estradiol tablets  
Ethinyl estradiol tablets &  
Ferrous fumarate tablets

**Review Number:** 1

## **Dates of Submission(s) Covered by this Review**

<b>Submit</b>	<b>Received</b>	<b>Review Request</b>	<b>Assigned to Reviewer</b>
March 26, 2009	March 27, 2009	September 16, 2009	September 17, 2009

**Submission History (for amendments only) – N/A**

## **Applicant/Sponsor**

**Name:** Warner Chilcott Company, Inc.  
**Address:** 100 Enterprise Drive, Roackaway, NJ 07866  
**Representative:** Alvin Howard, Sr. Vice President, RA  
**Telephone:** 973-442-3233

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

**Conclusion:** The NDA is approvable upon resolution of the deficiency listed in the Product Quality Microbiology Assessment, Section 3.

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## Product Quality Microbiology Data Sheet

- A. 1. TYPE OF SUBMISSION:** Original NDA
- 2. SUBMISSION PROVIDES FOR:** A new drug application.
- 3. MANUFACTURING SITE:** Warner Chilcott Co. Inc., Fajardo, PR 00738
- 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Oral Tablets in 1mg NA, 10 mcg EE and 10 mcg EE.
- 5. METHOD(S) OF STERILIZATION:** Non-sterile product.
- 6. PHARMACOLOGICAL CATEGORY:** Prevention of pregnancy.
- B. SUPPORTING/RELATED DOCUMENTS:** None.
- C. REMARKS:** The consult requests review of NDA 22-501 an oral drug product (b) (4) (Norethindrone acetate & Ethinyl estradiol tablets, Ethinyl estradiol tablets & Ferrous fumarate tablets) for product quality microbiology review. The applicant proposes no microbial testing for the oral tablets.

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**Executive Summary**

**I. Recommendations**

- A. Recommendation on Approvability** – This submission is approvable pending resolution of the deficiency listed in Product Quality Microbiology Assessment Section 3 of this review.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

**II. Summary of Microbiology Assessments**

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – WC3016 1/10 tablets are made

(b) (4)  


- B. Brief Description of Microbiology Deficiencies** – Microbial Limits test is not performed.
- C. Assessment of Risk Due to Microbiology Deficiencies** – a medium risk due to inability to assess microbial contamination in the product.

**III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
**Vinayak B. Pawar, Ph.D.**
- B. Endorsement Block** \_\_\_\_\_  
**Stephen E. Langille, Ph.D.**
- C. CC Block**  
N/A

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Application  
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Submitter Name

Product Name

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NDA-22501

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WARNER  
CHILCOTT CO INC

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 (b) (4)

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/s/  
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VINAYAK B PAWAR  
11/24/2009

STEPHEN E LANGILLE  
11/25/2009