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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.

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

3 Page(s) has ben Withheld in Full as b4 (CCI/TS) immediately following this page

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22501

ORIG-1

WARNER
CHILCOTT CO INC

 (b) (4)

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

/s/

VINAYAK B PAWAR
12/23/2009

STEPHEN E LANGILLE
12/23/2009

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