## CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 022501Orig1s000

**CHEMISTRY REVIEW(S)** 



lication:

NDA 22501/000

**Action Goal:** 

Stamp Date:

26-MAR-2009

**District Goal:** 

22-AUG-2010

Regulatory:

21-OCT-2010

Applicant:

WARNER CHILCOTT CO

**Brand Name:** 

(b) (4)

100 ENTERPRISE DR STE 280

Estab. Name:

norethindrone acetate and ethinyl estradiol

tablets, ethinyl estradiol tablets,

ROCKAWAY, NJ 07866

Generic Name:

Priority: Org. Code: 38 580

Product Number; Dosage Form; Ingredient; Strengths

001; TABLET; NORETHINDRONE ACETATE; 1MG

001; TABLET; ETHINYL ESTRADIOL; 10UGM 003; TABLET; FERROUS FUMARATE; POTENCY NOT GIVEN

002; TABLET; ETHINYL ESTRADIOL; 10UGM

**Application Comment:** 

THIS NDA IS FOR A LOW DOSE ORAL CONTRACEPTIVE, CONSISTING OF 10 MCG OF ETHINYL ESTRADIOL USP (EE) AND 1 MG OF NORETHINDRONE ACETATE USP (NA) DAILY FOR 24 DAYS, FOLLOWED BY A DAILY DOSE OF 10 MCG OF ETHINYL ESTRADIOL USP FOR 2 DAYS, THEN FERROUS FUMARATE FOR 2 DAYS. (on 29-APR-2009 by J. DAVID

() 301-796-4247)

THIS IS AN NDA RESUBMISSION (CLASS 2, 6 MONTH REVIEW CLOCK). THE NDA PDUFA GOAL DATE IS: 21-OCT-

2010. (on 03-MAY-2010 by J. DAVID () 301-796-4247)

**FDA Contacts:** 

C. TRAN-ZWANETZ

Project Manager

(HFD-800)

301-796-3877

Y. TANG

**Review Chemist** 

301-796-2457

D. CHRISTNER

Team Leader

301-796-1341

**Overall Recommendation:** 

**ACCEPTABLE** WITHHOLD

on 26-MAY-2010

by A. INYARD

()

on 19-JAN-2010

by E. JOHNSON

(HFD-320)

301-796-3334

Am inspany inner



blishment:

**CFN:** (b) (4)

**FEI:** (b) (4)

DMF No:

AADA:

Responsibilities:

DRUG SUBSTANCE OTHER TESTER

FINISHED DOSAGE OTHER TESTER

Estab. Comment:

THIS SITE IS FOR CONTRACT ANALYTICAL TESTING OF DRUG SUBSTANCES AND INACTIVE COMPONENTS. (on 29-

APR-2009 by J. DAVID () 301-796-4247)

THE ADDRESS GIVEN FOR THIS SITE IN THE NDA IS:

THIS ADDRESS IS CONFIRMED ON THE FIRM'S WEBSITE FOR ANALYTICAL TESTING. (THE ADDRESS (b) (4) ADDRESS.) THE FULL EMAIL FOR THE CONTACT AT THIS SITE GIVEN IN THE NDA IS:

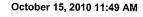
(b) (4) (on 03-MAY-2010 by J. DAVID () 301-796-4247)

Profile:

CONTROL TESTING LABORATORY

OAI Status: NONE

| Milestone Name    | Milestone Date | Request Type | Planned Completion | Decision     | Creator          |
|-------------------|----------------|--------------|--------------------|--------------|------------------|
| Comment           |                |              |                    | Reason       |                  |
| SUBMITTED TO OC   | 29-APR-2009    |              |                    |              | DAVIDJE          |
|                   |                | *****        | egenbere eleka     |              |                  |
| OC RECOMMENDATION | 01-MAY-2009    |              | e e                | ACCEPTABLE   | <b>FERGUSONS</b> |
|                   |                |              |                    | BASED ON PRO | FILE             |
|                   |                |              |                    |              |                  |
| SUBMITTED TO OC   | 03-MAY-2010    |              |                    |              | DAVIDJE          |
|                   |                |              |                    |              |                  |
| OC RECOMMENDATION | 03-MAY-2010    |              | •                  | ACCEPTABLE   | STOCKM           |
|                   |                |              |                    |              |                  |
|                   |                |              |                    | BASED ON PRO | FILE             |



(b) (4)



| ablishment: | <b>CFN:</b> (b) (4) | maria de la maria del | FEI:  | (b) (4) | 2 |
|-------------|---------------------|-----------------------|-------|---------|---|
|             |                     | (b) (4)               |       |         |   |
|             |                     | (b) (4)               |       |         |   |
| DMF No:     | (b) (4)             |                       | AADA: |         |   |

Responsibilities: DRUG SUBSTANCE MANUFACTURER

(b) (4)

Estab. Comment: THIS SITE IS FOR DRUG SUBSTANCE MANUFACTURE FOR ETHINYL ESTRADIOL USP AND NORETHINDRONE ACETATE

USP. (on 24-APR-2009 by J. DAVID () 301-796-4247)

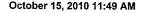
 $^{\rm (b)\,(4)}$  (NOT FOUND IN EES DATABASE). THE FULL ADDRESS GIVEN  $^{\rm (b)\,(4)}$ THE FEI NUMBER PROVIDED IN THE NDA IS

IN THE NDA IS:

(b) (4). (on 03-MAY-2010 by J. DAVID () 301-796-4247)

NON-STERILE BULK BY CHEMICAL SYNTHESIS Profile: OAI Status: NONE

| Milestone Name  Comment                | Milestone Date | Request Type   | Planned Completion       | Decision                       | Creator                   |
|--|----------------|----------------|--------------------------|--------------------------------|---------------------------|
| SUBMITTED TO OC                        | 29-APR-2009    |                |                          | Reason                         | DAVIDJE                   |
| SUBMITTED TO DO                        | 01-MAY-2009    | 10-Day Letter  | e eminación de la lación |                                | STOCKM                    |
| ASSIGNED INSPECTION TO IB              | 04-MAY-2009    | GMP Inspection |                          |                                | JOHNSONE                  |
| DO RECOMMENDATION                      | 19-JAN-2010    |                |                          | WITHHOLD PEND REG ACTION       | JOHNSONE<br>- WARNING LTR |
| OC RECOMMENDATION                      | 19-JAN-2010    |                |                          | WITHHOLD DISTRICT RECOMM       | JOHNSONE<br>ENDATION      |
| INSPECTION PERFORMED See EIR in Turbo. | 12-FEB-2010    |                | 12-FEB-2010              |                                | MCASALE                   |
| DO RECOMMENDATION                      | 09-APR-2010    |                |                          | ACCEPTABLE BASED ON FILE REV   |                           |
| OC RECOMMENDATION                      | 12-APR-2010    |                |                          | ACCEPTABLE DISTRICT RECOMM     | JOHNSONE                  |
| SUBMITTED TO OC                        | 03-MAY-2010    | Hoper Time     | The state of the         |                                | DAVIDJE                   |
| OC RECOMMENDATION                      | 03-MAY-2010    |                |                          | ACCEPTABLE<br>BASED ON PROFILE | STOCKM                    |









 Ablishment:
 CFN:
 (b) (4)
 FEI:
 (b) (4)

 DMF No:
 (b) (4)
 AADA:
 (b) (4)

Responsibilities: DRUG SUBSTANCE (b) (4)

Estab. Comment: THIS SITE IS FOR DRUG SUBSTANCE (b) (4) FOR ETHINYL ESTRADIOL USP AND NORETHINDRONE

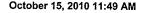
ACETATE USP. (on 24-APR-2009 by J. DAVID () 301-796-4247)

THE FULL ADDRESS GIVEN IN THE NDA IS (b) (4)

Profile: NON-STERILE BULK BY CHEMICAL SYNTHESIS OAI Status: NONF

Profile: NON-STERILE BULK BY CHEMICAL SYNTHESIS OAI Status: NONE

Milestone Name Milestone Date Request Type Planned Completion Decision Creator Comment Reason SUBMITTED TO OC 29-APR-2009 DAVIDJE OC RECOMMENDATION 01-MAY-2009 ACCEPTABLE STOCKM INSPECTION CONDUCTED (b) (4) COVERED THE CSN PROFILE; CLASSIFIED NAI. **BASED ON PROFILE** SUBMITTED TO OC 03-MAY-2010 DAVIDJE OC RECOMMENDATION 03-MAY-2010 **ACCEPTABLE** STOCKM BASED ON PROFILE





# DOCKET

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