

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**022501Orig1s000**

**CHEMISTRY REVIEW(S)**

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

<b>Application:</b>	NDA 22501/000	<b>Action Goal:</b>	
<b>Receipt Date:</b>	26-MAR-2009	<b>District Goal:</b>	22-AUG-2010
<b>Regulatory:</b>	21-OCT-2010		
<b>Applicant:</b>	WARNER CHILCOTT CO 100 ENTERPRISE DR STE 280 ROCKAWAY, NJ 07866	<b>Brand Name:</b>	(b) (4)
		<b>Estab. Name:</b>	norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets,
		<b>Generic Name:</b>	
<b>Priority:</b>	3S	<b>Product Number; Dosage Form; Ingredient; Strengths</b>	
<b>Org. Code:</b>	580		001; TABLET; NORETHINDRONE ACETATE; 1MG 001; TABLET; ETHINYL ESTRADIOL; 10UGM 003; TABLET; FERROUS FUMARATE; POTENCY NOT GIVEN 002; TABLET; ETHINYL ESTRADIOL; 10UGM
<b>Application Comment:</b>	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)		
<b>FDA Contacts:</b>	C. TRAN-ZWANETZ	Project Manager	(HFD-800) 301-796-3877
	Y. TANG	Review Chemist	301-796-2457
	D. CHRISTNER	Team Leader	301-796-1341

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<b>Overall Recommendation:</b>	ACCEPTABLE	on 26-MAY-2010	by A. INYARD	()
	WITHHOLD	on 19-JAN-2010	by E. JOHNSON	(HFD-320) 301-796-3334

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**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

**Establishment:** CFN: (b) (4) FEI: (b) (4)  
(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: (b) (4)  
THIS ADDRESS IS CONFIRMED ON THE FIRM'S WEBSITE FOR ANALYTICAL TESTING. (THE ADDRESS (b) (4)  
(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

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	29-APR-2009				DAVIDJE
OC RECOMMENDATION	01-MAY-2009			ACCEPTABLE BASED ON PROFILE	FERGUSONS
SUBMITTED TO OC	03-MAY-2010				DAVIDJE
OC RECOMMENDATION	03-MAY-2010			ACCEPTABLE BASED ON PROFILE	STOCKM

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

**Establishment:** CFN: (b) (4) FEI: (b) (4)  
 (b) (4)  
 (b) (4)  
**DMF No:** (b) (4) **AADA:**  
 (b) (4)  
**Responsibilities:** DRUG SUBSTANCE MANUFACTURER  
**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). THE FEI NUMBER PROVIDED IN THE NDA IS (b) (4) (NOT FOUND IN EES DATABASE). THE FULL ADDRESS GIVEN IN THE NDA IS: (b) (4) (on 03-MAY-2010 by J. DAVID () 301-796-4247)  
**Profile:** NON-STERILE BULK BY CHEMICAL SYNTHESIS **OAI Status:** NONE

<u>Milestone Name</u>	<u>Milestone Date</u>	<u>Request Type</u>	<u>Planned Completion</u>	<u>Decision</u>	<u>Creator</u>
<u>Comment</u>				<u>Reason</u>	
SUBMITTED TO OC	29-APR-2009				DAVIDJE
SUBMITTED TO DO	01-MAY-2009	10-Day Letter			STOCKM
ASSIGNED INSPECTION TO IB	04-MAY-2009	GMP Inspection			JOHNSONE
DO RECOMMENDATION	19-JAN-2010			WITHHOLD PEND REG ACTION - WARNING LTR	JOHNSONE
OC RECOMMENDATION	19-JAN-2010			WITHHOLD DISTRICT RECOMMENDATION	JOHNSONE
INSPECTION PERFORMED See EIR in Turbo.	12-FEB-2010		12-FEB-2010		MCASALE
DO RECOMMENDATION	09-APR-2010			ACCEPTABLE BASED ON FILE REVIEW	JOHNSONE
OC RECOMMENDATION	12-APR-2010			ACCEPTABLE DISTRICT RECOMMENDATION	JOHNSONE
SUBMITTED TO OC	03-MAY-2010				DAVIDJE
OC RECOMMENDATION	03-MAY-2010			ACCEPTABLE BASED ON PROFILE	STOCKM

**FDA CDER EES  
ESTABLISHMENT EVALUATION REQUEST  
DETAIL REPORT**

**Establishment:** CFN: (b) (4) FEI: (b) (4)  
 (b) (4)  
 (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) (b) (4)  
 (b) (4) (on 03-MAY-2010 by J. DAVID () 301-796-4247)

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

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

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