CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203567Orig1s000

CHEMISTRY REVIEW(S)

Memorandum	Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research
Date:	27-May-2014
To:	CMC Review #2 for NDA 203567
From:	Bogdan Kurtyka, Ph.D. CMC Reviewer, ONDQA Division II
Through:	Moo-Jhong Rhee, Ph.D. Chief, Branch IV ONDQA Division II
CC:	Shulin Ding, Ph.D. CMC Lead, ONDQA Division II
Subject:	**Final CMC Recommendation**

Previous CMC Review #2 dated 08-May-2014 and entered into DARRTS system on 09-May-2014 noted the following deficiencies which resulted in the recommendation of "Non Approval" action.

1. The Office of Compliance has ***not*** issued an overall "Acceptable" recommendation.
2. Unresolved label/labeling issues

Regarding Item #1:

On 27-May-2014 the Office of Compliance issued an overall "Acceptable" recommendation for establishments (see the **Attachment 1**).

Regarding Item #2,

On 16-May-2014 and 23-May-2014, the applicant submitted finalized label/labeling which are satisfactory from the ONDQA's perspective (see the **Attachment 2**).

Recommendation:

Because these issues were resolved satisfactorily, from the ONDQA perspective, this NDA is now recommended for **Approval** with expiration dating period of 36-month for all container/closure configurations.

Attachment 1: EES Summary Report

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application:	NDA 203567/000	**Sponsor:**	DOW PHARM
Org. Code:	540		1330 REDWOOD WAY
Priority:	1		PETALUMA, CA 94954
Stamp Date:	26-JUL-2012	**Brand Name:**	JUBLIA (EFINACONAZOLE) TOPICAL SOLUTION,
PDUFA Date:	20-JUN-2014	**Estab. Name:**	(EFINACONAZOLE) TOPICAL SOLUTION, 10%
Action Goal:		**Generic Name:**	
District Goal:	21-APR-2014	**Product Number; Dosage Form; Ingredient; Strengths**	001; SOLUTION; EFINACONAZOLE; 10%

FDA Contacts:	B. KURTYKA	Prod Qual Reviewer		3017961431
	C. TRAN-ZWANETZ	Product Quality PM	(HFD-800)	3017963877
	S. DIXON	Regulatory Project Mgr	(HFD-540)	3017961015
	S. DING	Team Leader		3017961349

Overall Recommendation:	ACCEPTABLE	on 27-MAY-2014	by T. WILSON	()	2404024226
	PENDING	on 23-JAN-2014	by EES_PROD		
	PENDING	on 06-JAN-2014	by EES_PROD		
	ACCEPTABLE	on 06-JAN-2014	by T. SHARP	()	3017963208
	PENDING	on 31-DEC-2013	by EES_PROD		
	ACCEPTABLE	on 09-MAY-2013	by J. WILLIAMS	()	3017964196
	PENDING	on 10-AUG-2012	by EES_PROD		
	PENDING	on 03-AUG-2012	by EES_PROD		
	PENDING	on 03-AUG-2012	by EES_PROD		

Establishment:	**CFN:** 2950819 **FEI:** 1000135370 DOW PHARMACEUTICAL SCIENCES PETALUMA, , UNITED STATES 949547122		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE RELEASE TESTER FINISHED DOSAGE RELEASE TESTER FINISHED DOSAGE STABILITY TESTER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	25-JAN-2013		
Decision:	ACCEPTABLE		
Reason:	DISTRICT RECOMMENDATION		

Establishment:	**CFN:** 9612799 **FEI:** 3002807376 KAKEN PHARMACEUTICAL CO., LTD. 301 GENSUKE FUJIEDA SHI 426 FUJIEDA-SHI, SHIZUOKA-KEN, JAPAN		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE RELEASE TESTER FINISHED DOSAGE MANUFACTURER FINISHED DOSAGE RELEASE TESTER		
Profile:	(b) (4) LIQUID (OTHER THAN SUSP & EMULSIONS)	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	27-MAY-2014		
Decision:	ACCEPTABLE		
Reason:	BASED ON PROFILE		

Establishment:	**CFN:** (b) (4) **FEI:** (b) (4) (b) (4)		
DMF No:		**AADA:**	
Responsibilities:	FINISHED DOSAGE RELEASE TESTER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	06-JAN-2014		
Decision:	ACCEPTABLE		
Reason:	DISTRICT RECOMMENDATION		

Establishment:	**CFN:** (b) (4) **FEI:** (b) (4) (b) (4)		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE OTHER TESTER		
Profile:	CONTROL TESTING LABORATORY	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	18-APR-2014		
Decision:	ACCEPTABLE		
Reason:	DISTRICT RECOMMENDATION		

Establishment:	**CFN:** (b) (4) **FEI:** (b) (4) (b) (4)		
DMF No:		**AADA:**	
Responsibilities:	DRUG SUBSTANCE MANUFACTURER DRUG SUBSTANCE STABILITY TESTER		
Profile:	(b) (4) API BY CHEMICAL SYNTHESIS	**OAI Status:**	NONE
Last Milestone:	OC RECOMMENDATION		
Milestone Date:	09-MAY-2013		
Decision:	ACCEPTABLE		
Reason:	DISTRICT RECOMMENDATION		

Attachment 2: Finalized labeling and labels

1. Package Insert

(a) "Highlights" Section

JUBLIA® (efinaconazole) topical solution, 10%
For topical use
Initial U.S. Approval: 2014

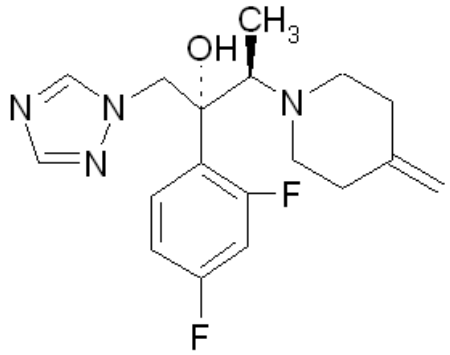
(b) "Full Prescribing Information" Section

3: Dosage Forms and Strengths

JUBLIA (efinaconazole) topical solution, 10% contains 100 mg of efinaconazole in each gram of clear, colorless to pale yellow solution.

#11: Description

JUBLIA contains 100 mg of efinaconazole. Efinaconazole is an azole antifungal with a chemical name of ((2R,3R)-2-(2,4-difluorophenyl)-3-(4-methylenepiperidin-1-yl)-1-(1H-1,2,4-triazol-1-yl) butan-2-ol). The structural formula for efinaconazole is represented below:



Molecular Formula: $C_{18}H_{22}F_2N_4O$ Molecular Weight: 348.39

JUBLIA contains the following inactive ingredients: alcohol, anhydrous citric acid, butylated hydroxytoluene, C12-15 alkyl lactate, cyclomethicone, diisopropyl adipate, disodium edetate, and purified water.

#16: How Supplied/Storage and Handling

JUBLIA (efinaconazole) topical solution, 10% is a clear, colorless to pale yellow solution supplied in a white plastic bottle with an integrated flow-through brush applicator as follows:

- 4 mL (NDC 0187-5400-04)
- 8 mL (NDC 0187-5400-08) Storage and Handling Conditions:

Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [see USP Controlled Room Temperature].

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