

3 DETAILED LABELING RECOMMENDATIONS

The following changes are recommended. ABC indicates deletion of text from and ABC indicates insertion of new text to the labeling text proposed by the Sponsor.

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

4 APPENDICES

4.1 Package Insert (Proposed and Annotated)

Please refer to \\Cdsub1\evsprod\NDA050819\0000\m1\us\114-labeling\1141-draft-labeling\11412-annotated-draft-labeling-text\annotated-draft-labeling-text.pdf

Appears This Way On Original

4.2 Summary of Individual Studies

No clinical pharmacology study was performed in humans for this application.

Appears This Way On Original

4.3 Consult Reviews

No consult review was requested.

Appears This Way On Original

4.4 OCPB Filing/Review Form

Office of Clinical Pharmacology and Biopharmaceutics New Drug Application Filing and Review Form				
General Information about the Submission				
	Information		Information	
NDA Number	50-819	Brand Name	(b) (4) Gel	
OCPB Division (I, II, III)	DCP3	Generic Name	1.2 % clindamycin phosphate, 2.5 % benzoyl peroxide	
Medical Division	HFD-540	Drug Class	Anti microbial	
OCPB Reviewer	Abi Adebowale	Indication(s)	Treatment of acne vulgaris in patients 12 years and older	
OCPB Team Leader	Lydia Velazquez	Dosage Form	Gel	
Letter Date	21 st December, 2007	Dosing Regimen	(b) (4)	
Application Receipt Date	26 th December, 2007	Route of Administration	Topical	
Estimated Due Date of OCPB Review	26 th August, 2008	Sponsor	Dow Pharmaceutical Sciences, Inc.	
PDUFA Due Date	26 th , October, 2008	Priority Classification	Standard 505 (b) (2) application <i>Reference Listed Drugs are Benzoclin Topical Gel and Duac Topical Gel</i>	
		IND Number	41,733	
Clin. Pharm. and Biopharm. Information				
	"X" if included at filing	Number of studies submitted	Number of studies reviewed	Study Numbers If any
STUDY TYPE				
Table of Contents present and sufficient to locate reports, tables, data, etc.	X			
Tabular Listing of All Human Studies	X			
HPK Summary	X			
Labeling	X			
Reference Bioanalytical and Analytical Methods	X			Sponsor needs to direct me to the validation report for the assay method used in study # 2104-047-051-053-056 (In vitro percutaneous absorption)
I. Clinical Pharmacology				
Mass balance:				
Isozyme characterization:				
Blood/plasma ratio:				
Plasma protein binding:				
Pharmacokinetics (e.g., Phase I) -				
Healthy Volunteers-				
single dose:				
multiple dose:				
Patients-				
single dose:				
multiple dose:				
Dose proportionality -				
fasting / non-fasting single dose:				
fasting / non-fasting multiple dose:				
Drug-drug interaction studies -				
In-vivo effects on primary drug:				
In-vivo effects of primary drug:				
In-vitro:				
Subpopulation studies -				
ethnicity:				
gender:				
pediatrics:				
geriatrics:				
renal impairment:				

hepatic impairment:				
PD:				
Phase 2:				
Phase 3:				
PK/PD:				
Phase 1 and/or 2, proof of concept:				
Phase 3 clinical trial:				
Population Analyses -				
Data rich:				
Data sparse:				
II. Biopharmaceutics				
Absolute bioavailability:				
Relative bioavailability -				
solution as reference:				
alternate formulation as reference (IR):				
Bioequivalence studies -				
traditional design; single / multi dose:	X	1		Study # DPS-07-07-2005-001- (b) (4) (b) (4)
replicate design; single / multi dose:				
Food-drug interaction studies:				
Dissolution:				
(IVTC):				
Bio-wavier request based on BCS				
BCS class				
III. Other CFB Studies				
Genotype/phenotype studies:				
Other (in vitro percutaneous absorption study)	X	1		Study #2104-047-051-053-056
Chronopharmacokinetics				
Pediatric development plan				
Literature References				
Total Number of Studies		2		
Filability and QBR comments				
Types and #'s of studies and supplementary information (literature review) are adequate to conduct a review	"X" if yes X	Comments Send IR to sponsor to direct me to, or provide, the validation report for the analytical method used to measure clindamycin, benzoyl peroxide and benzoic acid in study #2104-047-051-053-056: In Vitro Percutaneous absorption of Clindamycin and Benzoyl peroxide from Benzacilin, (b) (4) (1/2.5), (b) (4) and DUAC Topical Gel using intact human skin from two healthy donors. Sponsor already responded		
Application filable?	X	Reasons if the application is not filable (or an attachment if applicable) For example, is clinical formulation the same as the to-be-marketed one?		
Comments sent to firm?	No	Comments have been sent to firm (or attachment included). FDA letter date if applicable.		
QBR questions (key issues to be considered)	What is the systemic exposure of clindamycin and benzoyl peroxide from (b) (4) Gel and how does it compare to the currently marketed products?			
Other comments or information not included above				
Primary reviewer Signature and Date	Abi Adebawale (02/11/08)			
Secondary reviewer Signature and Date	Lydia Velazquez			

End of Document

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this page is the manifestation of the electronic signature.**

/s/

Jang-Ik Lee
9/29/2008 03:21:40 PM
BIOPHARMACEUTICS

Lydia Velazquez
9/29/2008 03:53:46 PM
BIOPHARMACEUTICS

Office of Clinical Pharmacology and Biopharmaceutics
New Drug Application Filing and Review Form

General Information about the Submission

	Information		Information
NDA Number	50-819	Brand Name	_____ Gel
OCPB Division (I, II, III)	DCP3	Generic Name	1.2 % clindamycin phospahte , 2.5 % benzoyl peroxide
Medical Division	HFD-540	Drug Class	Anti microbial
OCPB Reviewer	Abi Adebowale	Indication(s)	Treatment of acne vulgaris in patients 12 years and older
OCPB Team Leader	Lydia Velazquez	Dosage Form	Gel
Letter Date	21 st December, 2007	Dosing Regimen	To be applied to the affected areas once daily or as directed by the physician
Application Receipt Date	26 th December, 2007	Route of Administration	Topical
Estimated Due Date of OCPB Review	26 th August, 2008	Sponsor	Dow Pharmaceutical Sciences, Inc.
PDUFA Due Date	26 th , October, 2008	Priority Classification	Standard 505 (b) (2) application <i>Reference Listed Drugs are Benzacclin Topical Gel and Duac Topical Gel</i>
		IND Number	41,733

b(4)

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(IVIVC):				
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QBR questions (key issues to be considered)	What is the systemic exposure of clindamycin and benzoyl peroxide from ——— Gel and how does it compare to the currently marketed products?			
Other comments or information not included above				
Primary reviewer Signature and Date	Abi Adebawale (02/11/08)			
Secondary reviewer Signature and Date	Lydia Velazquez			

b(4)

CC: NDA 50-819, HFD-850 (P.Lee), HFD-540 (T.White, M. Owens), DCP 3 (D. Bashaw, L. Velazquez)

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/s/

Abi Adebawale
6/5/2008 10:53:10 AM
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