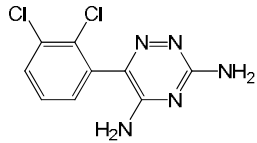


CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:
22-509**

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW #1		1. ORGANIZATION		2. NDA NUMBER	
		ONDQA		022509	
3. NAME AND ADDRESS OF APPLICANT				4. SUPPLEMENT (S)	
SmithKline Beecham Corporation d/b/a GlaxoSmithKline One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102.				NUMBER(S)	DATE(S)
				N 000	03/31/2009
5. PROPRIETARY NAME		6. NAME OF THE DRUG		7. AMENDMENTS, REPORT, DATE	
Lamictal® XR™		Lamotrigine		07/28/2009 11/06/2009	
8. SUPPLEMENT PROVIDES FOR:					
for adjunctive treatment of Primary Generalized Tonic-Clonic (PGTC) Seizures in patients 13 years of age and older					
9. PHARMACOLOGICAL CATEGORY		10. HOW DISPENSED		11. RELATED IND, NDA, DMF	
		RX <input checked="" type="checkbox"/> OTC			
12. DOSAGE FORM		13. POTENCY			
Tablets		25 mg 50 mg 100 mg 200 mg			
14. CHEMICAL NAME AND STRUCTURE				15. RECORDS AND REPORTS	
3,5-diamino-6-(2,3-dichlorophenyl)-as-triazine  Chemical Formula: C ₉ H ₇ Cl ₂ N ₅ Molecular Weight: 256.09					
16. COMMENTS					
This Type 6 NDA provides for adjunctive treatment of Primary Generalized Tonic-Clonic (PGTC) Seizures in patients 13 years of age and older. The CMC section for this NDA is contained in the original NDA 22-115. This application also contained Quality data for (b) (4) and 300 mg Tablets. This section was withdrawn from the application on 07/28/2009 and resubmitted as S-001 for N 22-115 on 07/31/2009. A Complete Response Letter was issued to N 22-115/S-001 seeking approval for these two strengths on 11/30/2009. An amended label was submitted on 11/06/2009 reflecting removal of the two strengths (b) (4) and 300 mg) from this NDA. The CMC sections of the label ("Dosage Forms and Strengths", "Description", and "How Supplied" of the PI and Med Guide) were found to be acceptable. <u>No other CMC issues or information were identified in this application.</u>					
17. CONCLUSION AND RECOMMENDATION					
This submission is recommended for approval from the stand point of chemistry, manufacturing and controls.					
18. REVIEWERS SIGNATURE				19. DATE COMPLETED	
See appended electronic signature sheet				December 3, 2009	
DISTRIBUTION:	ORIGINAL JACKET	DIVISION FILE	REVIEWER	CSO	BRANCH CHIEF
			Anamitro Banerjee, Ph.D.	D. Demczar	J. Vidra, Ph.D.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22509	ORIG-1	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLIN E	LAMICTAL XR(LAMOTRIGINE)ORAL TABLETS

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

/s/

ANAMITRO BANERJEE
12/03/2009

NALLAPERUM CHIDAMBARAM
12/03/2009
For Dr. James D. Vidra