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Approval Package for:

APPLICATION NUMBER:

022255Orig1s000

Trade Name:	**VIMPAT ORAL SOLUTION, 10 mg/ml**
Generic Name:	**Lacosamide**
Sponsor:	**UCB/Schwarz Biosciences, Inc**
Approval Date:	**April 20, 2010**
Indications:	**For the use of Vimpat (lacosamide) Oral Solution as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older**.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022255, 022253/S-006, 022254/S-003 **NDA APPROVAL**

Schwarz Biosciences, Inc.
Attention: Susan Tegtmeyer, M. S.
Senior Manager Regulatory Affairs
1950 Lake Park Drive
Smyrna, GA 30080

Dear Ms. Tegtmeyer:

Please refer to your September 28, 2007, New Drug Application (NDA) 022255, received September 28, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vimpat (lacosamide) Oral Solution, 10 mg/ml.

We acknowledge receipt of your submissions to NDA 022255 dated October 16, 2009, and February 4, March 31, and April 20, 2010.

The October 16, 2009, submission constituted a complete response to our October 28, 2008, action letter.

This new drug application provides for the use of Vimpat (lacosamide) Oral Solution as adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy aged 17 years and older.

We further refer to your August 21, 2009, supplemental NDAs 022253/S-006 and 022254/S-003, received August 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vimpat (lacosamide) Tablets and Injection. These supplements provide for a comprehensive Medication Guide and modified risk evaluation and mitigation strategy (REMS).

We acknowledge receipt of your submissions to NDAs 022253/S-006 and 022254/S-003 dated October 5 and 6, 2009, and March 31, and April 13, 2010. Finally, we acknowledge receipt of your April 20, 2010 amendments to NDAs 022253/S-006 and 022254/S-003 containing a modified REMS and REMS assessment.

We have completed our review of these applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert and Medication Guide). For administrative purposes, please designate this submission, "**SPL for approved NDAs 022255, 022253/S-006, and 022254/S-003."**

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on April 15, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 022255."** Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 1 month for these applications because necessary studies are impossible or highly impracticable because there are too few children with partial onset seizures in this age group to study.

In addition, we are deferring submission of your pediatric studies in partial onset seizures for ages 1 month up to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. This required study is listed below.

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