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***APPLICATION NUMBER:***

**022255Orig1s000**

# SUMMARY REVIEW

**MEMORANDUM**

DATE: April 19, 2010

FROM: Director
Division of Neurology Products/HFD-120

TO: File, NDA 22-255

SUBJECT: Action Memo for NDA 22-255, for the use of Vimpat (lacosamide) Oral Solution, 10 mg/mL and for NDA 22-253/S-006 for Vimpat (lacosamide) Tablets & NDA 22-254/S-003, for Vimpat (lacosamide) Injection

NDA 22-255, for the use of Vimpat (lacosamide) Oral Solution, was submitted by Schwarz Biosciences, Inc., on 9/27/07. NDAs 22-253 and 22-254, for Vimpat Tablets and Injection, respectively, were approved on 10/28/08, for the adjunctive treatment of partial seizures in patients aged 17 years and older. NDA 22-255, for Vimpat oral solution, submitted at the same time as NDAs 22-253 and 22-254, was not approved. Specifically, the Agency issued a Complete Response (CR) letter on 10/28/08 for Vimpat Oral Solution because the concentration of the solution proposed in that NDA (b) (4) did not permit the prescribed doses to be achieved accurately. (b) (4) The Agency was concerned that medication errors could have occurred (b) (4) .

For these reasons, we had proposed that the sponsor develop a solution with a different concentration. We noted in the CR letter that the sponsor had previously developed a 10 mg/mL syrup, and we implied that such a concentration might be more appropriate.

The sponsor responded to the CR letter with a complete response on 10/16/09, in which they proposed a 10 mg/mL oral solution. This submission has been reviewed by Dr. Wendy Wilson-Lee, chemist in the Office of New Drug Quality Assessment (ONDQA), Dr. Ramesh Sood, Branch Chief, ONDQA, Dr. Tien-Mien Chen, biopharmaceutics reviewer, ONDQA, and Dr. Judy Park, Division of Medication Error Prevention and Analysis (DMEPA). The review team recommends that the application be approved.

I agree. Adequate chemistry information has been provided, there is no requirement that the proposed formulation be shown to be bioequivalent to any approved formulation (as Dr. Chen points out, the previous 10 mg/mL formulation

had been shown to be bioequivalent to the tablet, and the solution is essentially 100% bioavailable), and dosing with the 10 mg/mL solution can be achieved with acceptable accuracy with commercially available measuring cups, spoons, etc.

The three lacosamide formulations share a common label including a Medication Guide, and there is a REMS in place for these products (all anti-epilepsy drugs are required to have Medication Guides, and therefore REMS, because of the finding of increased suicidality for this class of drugs). Because the Medication Guide had to be amended to include a description of the oral solution, the REMS needed to be amended. Because the tablets and injection were approved under separate NDAs, the REMS needed to be amended for these previous products. For this reason, Supplement 006 for the Tablets (NDA 22-253) and Supplement 003 for the injection (NDA 22-254) were submitted on 8/21/09.

For these reasons, I will issue the attached Approval letter for NDA 22-255, and for the associated NDAs 22-253/S-006 and 22-254/S-003, with appended agreed-upon product labeling.

Russell Katz, M.D.

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-22255 | ORIG-1 | SCHWARZ BIOSCIENCES INC | VIMPAT |

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

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/s/

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RUSSELL G KATZ
04/20/2010