

North Central Cancer Treatment Group

N0779: Phase II Study of Vorinostat (SAHA) in Combination with Bortezomib (PS-341) in Patients with Recurrent Glioblastoma Multiforme

Addendum 2 – November 21, 2008

Summary

Oxcarbazepine is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6. Therefore, reference to Oxcarbazepine has been deleted from the eligibility criteria (Section 3.39c).

Replacement pages are included. Please incorporate into the protocol and keep this addendum with your protocol.

Title page Updated to reflect the addition of Addendum 2 and revised NCI version date.

Section 3.0 **Patient Eligibility**

Page 17: Reference to Oxcarbazepine has been deleted from Section 3.39c as follows as this drug is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6:
Receiving enzyme-inducing antiepileptic drugs (EIACs; *e.g.*, phenytoin, fosphenytoin, carbamazepine, ~~oxcarbazepine~~, phenobarbital, or primidone) or any other potent CYP3A4 inducer such as rifampin or St. John's wort.

Appendix V **Comprehensive List of Drugs That May Have Potential Interactions**

Page 1: Reference to Oxcarbazepine has been deleted in the table as follows as this drug is not considered a major inducer or inhibitor of CYP3A4 or CYP2A6:

<i>Inducers</i>			
Aminoglutethimide	Nevirapine	Phenytoin	Rifapentine
Carbamazepine	Oxcarbazepine	Primidone	
Fosphenytoin	Pentobarbital	Rifabutin	
St. John's wort	Phenobarbital	Rifampin	