

IND Exemption Justification

Study Title / No.	A RANDOMIZED, PHASE III, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF MEMANTINE FOR PREVENTION OF COGNITIVE DYSFUNCTION IN PATIENTS RECEIVING WHOLE-BRAIN RADIOTHERAPY	0614
-------------------	---	------

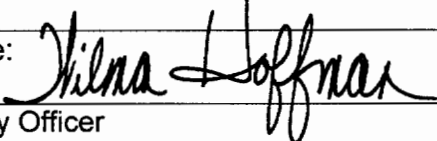
Review criteria for IND Exemption per 21 CFR Part 312.2(B) (1) (1-5)

IND Exemption Criteria	Criteria Met
1. The study is not intended to support FDA approval of a new indication or a significant change in the product labeling.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2. The study is not intended to support a significant change in the advertising for the product.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3. The investigation does not involve a route of administration of dosage level or use in a patient population or other factor that <i>significantly increases the risks</i> (or decreases the acceptability of the risks) associated with the use of the drug product.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4. The study is conducted in compliance with institutional review board (IRB) and informed consent regulations set forth in parts 56 and 50 (21 CFR parts 56 and 50).	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5. The study is conducted in compliance with §312.7 (promotion and charging for investigational drugs).	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Recommendation:

I have reviewed this proposal to determine if the regulations pertaining to the requirements for filing an IND application to perform this trial of marketed agents for the treatment of patients for (The prevention of cognitive dysfunction in patients receiving whole-brain radiation). It is my opinion that this trial meets the criteria for a claimed exemption from the IND regulations as defined in 21 CFR Part 312.2 (b)(1-5) and recommend to the Group this study may be considered exempt from the requirements of an IND filing.

Signature:



Regulatory Officer
 Wilma Hoffman

Date
 1/7/08