

12.

### CONTENTS OF APPLICATION

This application contains the following items: (Check all that apply)

- 1. Form FDA 1571 [21 CFR 312.23(a)(1)]
- 2. Table of Contents [21 CFR 312.23(a)(2)]
- 3. Introductory statement [21 CFR 312.23(a)(3)]
- 4. General Investigational plan [21 CFR 312.23(a)(3)]
- 5. Investigator's brochure [21 CFR 312.23(a)(5)]
- 6. Protocol(s) [21 CFR 312.23(a)(6)]
  - a. Study protocol(s) [21 CFR 312.23(a)(6)]
  - b. Investigator data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
  - c. Facilities data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
  - d. Institutional Review Board data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
- 7. Chemistry, manufacturing, and control data [21 CFR 312.23(a)(7)]
  - Environmental assessment or claim for exclusion [21 CFR 312.23(a)(7)(iv)(e)]
- 8. Pharmacology and toxicology data [21 CFR 312.23(a)(8)]
- 9. Previous human experience [21 CFR 312.23(a)(9)]
- 10. Additional information [21 CFR 312.23(a)(10)]

13. IS ANY PART OF THE CLINICAL STUDY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION?  YES  NO

IF YES, WILL ANY SPONSOR OBLIGATIONS BE TRANSFERRED TO THE CONTRACT RESEARCH ORGANIZATION?  YES  NO

IF YES, ATTACH A STATEMENT CONTAINING THE NAME AND ADDRESS OF THE CONTRACT RESEARCH ORGANIZATION, IDENTIFICATION OF THE CLINICAL STUDY, AND A LISTING OF THE OBLIGATIONS TRANSFERRED.

14. NAME AND TITLE OF THE PERSON RESPONSIBLE FOR MONITORING THE CONDUCT AND PROGRESS OF THE CLINICAL INVESTIGATIONS

[REDACTED]

15. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF INFORMATION RELEVANT TO THE SAFETY OF THE DRUG

[REDACTED]

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

16. NAME OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

[REDACTED]

17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE

[REDACTED]

18. ADDRESS (Number, Street, City, State and Zip Code)

[REDACTED]

19. TELEPHONE NUMBER (Include Area Code)

[REDACTED]

20. DATE  
04/01/2010

**(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)**

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Beltsville, MD 20705-1266

Department of Health and Human Services  
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