PUBLIC HEA	HEALTH AND HUMAN SERVICES C HEALTH SERVICE DRUG ADMINISTRATION		Form Approved: OMB No. 0910-0014. Expiration Date: December 31, 1999 See OMB Statement on Reverse.		
INVESTIGATIONAL NEW	DRUG APPLICATION (IN REGULATIONS (CFR) PART 312)		Note: No drug may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40).		
1. NAME OF SPONSOR			2. DATE OF	SUBMISSION	
3. ADDRESS (Number, Street, City, State and Zip Code))		4. TELEPHO (Include	NE NUMBER Area Code)	
5. NAME(S)OF DRUG (Include all available names: Tra	de, Generic, Chemical, Code)		6. IND NUME	BER (If previously assigned)	
7. INDICATIONS(S) (Covered by this submission)			<u>I</u>		
8. PHASE(S) OF CLINICAL INVESTIGATION TO BE CO	DNDUCTED:	SE 2 🔲 PHASE :	3 🗌 OTHER	(Specify)	
9. LIST NUMBERS OF ALL INVESTIGATIONAL NEW I (21 CFR Part 314) DRUG MASTER FILES (21 CFR F TO IN THIS APPLICATION.					
10. IND submission should be consecutiv "Serial number: 000." The next submi- should be numbered "Serial Number: consecutively in the order in which th	ssion (e.g., amendment, report, or 001." Subsequent submissions sh	corresponde	ence)	SERIAL NUMBER	
11. THIS SUBMISSION CONTAINS THE FOLLOWING:		□ F	RESPONSE TO	CLINICAL HOLD	
PROTOCOL AMENDMENT(S):	INFORMATION AMENDMENT(S):		IND SAFETY	'REPORT(S):	
NEW PROTOCOL CHANGE IN PROTOCOL NEW INVESTIGATOR	CHEMISTRY/MICROBIOLOGY		INITIAL WRITTEN REPORT		
RESPONSE TO FDA REQUEST FOR INFORMATION REQUEST FOR REINSTATEMENT OF IND THAT IS INACTIVATED, TERMINATED OR DISCONTINUED] OTHER	GENE		
			(Specify)		
	CHECK ONLY IF APPLICAE	BLE			
JUSTIFICATION STATEMENT MUST BE SUBMI SECTION FOR FURTHER INFORMATION.	TTED WITH APPLICATION FOR ANY C	HECKED BEL	OW. REFER 1	TO CITED CFR	
TREATMENT IND 21 CFR 312.35(b)			REQUEST/NO	OTIFICATION 21 CFR312.7(d)	
CDR/BIND/DGD RECEIPT STAMP	FOR FDA USE ONLY DDR RECEIPT STAMP		DIVISI	ON ASSIGNMENT:	
				JMBER ASSIGNED:	
EORM EDA 1571 (1/07)			I	PACE 1 OE 2	

This application contains the following items: (<i>Check all that apply</i>) 12. 12. 11. Form FDA 1571 [21 CFR 312.23(a)(1)] 12. Table of Contents [21 CFR 312.23(a)(3)] 13. Introductory statement [21 CFR 312.23(a)(3)] 14. General Investigational plan [21 CFR 312.23(a)(5)] 15. Investigator's brochure [21 CFR 312.23(a)(6)] 16. Protocol(5) [21 CFR 312.23(a)(6)] 17. Investigation and 12 (CFR 312.23(a)(6)] 18. Investigation and 12 (CFR 312.23(a)(6))[(in)(b)] or completed Form(s) FDA 1572 19. A Facilitation and Review Board data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572 19. Chemistry, manufacturing, and control data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572 10. Additional Review Board data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572 11. Rest manufacturing, and control data [21 CFR 312.23(a)(7)] 10. Forthometal assessment or claim for exclusion [21 CFR 312.23(a)(7)] 10. Additional information [21 CFR 312.23(a)(9)] 11. Additional information [21 CFR 312.23(a)(9)] 12. SAWP PART OF THE CUNCAL STUPY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION? YES [] NO IF YES, WILL ANY SPONSOR OBLIGATIONS TRANSFERRED. DO IF YES, WILL ANY SPONSOR OBLIGATIONS TRANSFERRED. DO IF YES, WILL ANY SPONSOR OBLIGATIONS TRANSFERRED. DO </th
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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, ATACH 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 15. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF THE INFORMATION RELEVANT TO THE SAFETY OF THE DRUG 14. 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'S AUTHORIZED 17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED 16. NAME OF SPONSOR'S AUTHORIZED 17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED
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(Include Area Code)
(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)
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