

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration
INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
 Expiration Date: February 28, 2019
 See PRA Statement on page 3.
 NOTE: No drug/biologic 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 (mm/dd/yyyy)
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3. Sponsor Address	4. Telephone Number (Include country code if applicable and area code)
Address 1 (Street address, P.O. box, company name c/o)	6A. IND Number (If previously assigned)
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City	State/Province/Region
Country	ZIP or Postal Code
6B. Select One: <input type="checkbox"/> Commercial <input type="checkbox"/> Research	

5. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)

Continuation Page for #5

7A. (Proposed) Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>

Continuation Page for #7

7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)

8. Phase of Clinical Investigation to be conducted Phase 1 Phase 2 Phase 3 Other (Specify): _____

9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted.	Serial Number _____
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11. This submission contains the following (Select all that apply)

<input type="checkbox"/> Initial Investigational New Drug Application (IND)	<input type="checkbox"/> Response to Clinical Hold	<input type="checkbox"/> Response To FDA Request For Information
<input type="checkbox"/> Request For Reactivation Or Reinstatement	<input type="checkbox"/> Annual Report	<input type="checkbox"/> General Correspondence
<input type="checkbox"/> Development Safety Update Report (DSUR)	<input type="checkbox"/> Other (Specify): _____	

Protocol Amendment	Information Amendment	Request for	IND Safety Report
<input type="checkbox"/> New Protocol	<input type="checkbox"/> Chemistry/Microbiology	<input type="checkbox"/> Meeting	<input type="checkbox"/> Initial Written Report
<input type="checkbox"/> Change in Protocol	<input type="checkbox"/> Pharmacology/Toxicology	<input type="checkbox"/> Proprietary Name Review	<input type="checkbox"/> Follow-up to a Written Report
<input type="checkbox"/> New Investigator	<input type="checkbox"/> Clinical/Safety <input type="checkbox"/> Statistics	<input type="checkbox"/> Special Protocol Assessment	
<input type="checkbox"/> PMR/PMC Protocol	<input type="checkbox"/> Clinical Pharmacology	<input type="checkbox"/> Formal Dispute Resolution	
<input type="checkbox"/> Human Factors Protocol			

12. For Originals, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No	Combination Product Type (See instructions)	Request for Designation (RFD) Number
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13. Select the following only if applicable. (Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.)

Expanded Access Use, 21 CFR 312.300

<input type="checkbox"/> Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f)	<input type="checkbox"/> Individual Patient, Non-Emergency 21 CFR 312.310	<input type="checkbox"/> Intermediate Size Patient Population, 21 CFR 312.315
<input type="checkbox"/> Charge Request, 21 CFR 312.8	<input type="checkbox"/> Individual Patient, Emergency 21 CFR 312.310(d)	<input type="checkbox"/> Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only

CBER/DCC Receipt Stamp	DDR Receipt Stamp	Division Assignment
		IND Number Assigned

14. Contents of Application – This application contains the following items (*Select all that apply*)

- | | |
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| <input type="checkbox"/> 1. Form FDA 1571 (21 CFR 312.23(a)(1))
<input type="checkbox"/> 2. Table of Contents (21 CFR 312.23(a)(2))
<input type="checkbox"/> 3. Introductory statement (21 CFR 312.23(a)(3))
<input type="checkbox"/> 4. General Investigational plan (21 CFR 312.23(a)(3))
<input type="checkbox"/> 5. Investigator's brochure (21 CFR 312.23(a)(5))
<input type="checkbox"/> 6. Protocol (21 CFR 312.23(a)(6)) <ul style="list-style-type: none"> <input type="checkbox"/> a. Study protocol (21 CFR 312.23(a)(6)) <input type="checkbox"/> b. Investigator data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572 <input type="checkbox"/> c. Facilities data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572 | 6. Protocol (<i>Continued</i>) <ul style="list-style-type: none"> <input type="checkbox"/> d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572 <input type="checkbox"/> 7. Chemistry, manufacturing, and control data (21 CFR 312.23(a)(7)) <ul style="list-style-type: none"> <input type="checkbox"/> Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e)) <input type="checkbox"/> 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
<input type="checkbox"/> 9. Previous human experience (21 CFR 312.23(a)(9))
<input type="checkbox"/> 10. Additional information (21 CFR 312.23(a)(10))
<input type="checkbox"/> 11. Biosimilar User Fee Cover Sheet (<i>Form FDA 3792</i>)
<input type="checkbox"/> 12. Clinical Trials Certification of Compliance (<i>Form FDA 3674</i>) |
|--|--|

15. 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, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred (*use continuation page*).

Continuation
Page for #14

16. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

17. Name and Title of the person responsible for review and evaluation of information relevant to the safety of the drug

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 or financial 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.

18. Name of Sponsor or Sponsor's Authorized Representative

19. Telephone Number (*Include country code if applicable and area code*)

20. Facsimile (FAX) Number (*Include country code if applicable and area code*)

21. Address

Address 1 (*Street address, P.O. box, company name c/o*)

Address 2 (*Apartment, suite, unit, building, floor, etc.*)

City

State/Province/Region

Country

ZIP or Postal Code

22. Email Address

23. Date of Sponsor's Signature (*mm/dd/yyyy*)

24. Name of Countersigner

25. Address of Countersigner

Address 1 (*Street address, P.O. box, company name c/o*)

Address 2 (*Apartment, suite, unit, building, floor, etc.*)

City

State/Province/Region

Country

ZIP or Postal Code

26. Email Address

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

27. Signature of Sponsor or Sponsor's Authorized Representative

Sign

28. Signature of Countersigner

Sign

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Please do NOT send your completed form to this PRA Staff email address.

CONTINUATION PAGE FOR ITEM 5 – Name of Drug

Name of Drug *(Include all available names: Trade, Generic, Chemical, Code) – Continue your answer in the space below.*

FIRST CONTINUATION PAGE FOR ITEM 7 – (Proposed) Indication for Use

Please fill out as many sets of answers as needed, completing all elements within each set that you start.

7A. (Proposed) Indication for Use	Is this indication for a rare disease (prevalence <200,000 in U.S.)? <input type="checkbox"/> Yes <input type="checkbox"/> No	
	Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, provide the Orphan Designation number for this indication: <input type="text"/>

7B. SNOMED CT Indication Disease Term

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SECOND CONTINUATION PAGE FOR ITEM 7 – (Proposed) Indication for Use

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7B. SNOMED CT Indication Disease Term

FIRST CONTINUATION PAGE FOR ITEM 14 – Information on Contract Research Organization

For each (as applicable below) contract service organization involved in the clinical study, please provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred.

Contract Service Organization

Contract Service Organization

Contract Service Organization

Contract Service Organization

Contract Service Organization

SECOND CONTINUATION PAGE FOR ITEM 14 – Information on Contract Research Organization

For each (as applicable below) contract service organization involved in the clinical study, please provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred.

Contract Service Organization

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