**INSTITUTION LOGO**

**INITIAL INVESTIGATIONAL NEW DRUG APPLICATION**

**DRUG TRADE NAME (GENERIC NAME)**

Date of Submission: MM DD, YY

Sponsor Name

Institution Name

Mailing Address

Mailing Address

Telephone

**CONFIDENTIAL**

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# Forms FDA 1571 and 3674

*Completed Form FDA 1571 and Form FDA 3674 should be referenced here as separate appendices.*

# Introduction

## Introductory Statement

*This section is brief; usually 2-3 pages should be sufficient. This section should contain information about the clinical indication and the reason that you think the product has a place in the treatment of these patients. The FDA is concerned primarily with safety of the participants of your study, so the scientific merit of the study does not have to be explored in depth in this section. It is best to state briefly why you believe this study is necessary and who will benefit from the study, then go into some more detail as to how the participants in the study are to be protected.*

*After your introductory statement, use the headings below to ensure you fulfill all of the requirements.* ***Maintain all of the headings*** *in this document and if not applicable to your IND, simply state this.*

### Name of the Drug and All Active Ingredients

### Pharmacological Class of the Drug

### Structural Formula of the Drug

### Formulation of the Dosage Forms to be Used

### Route of Administration

### Objectives and Duration of the Proposed Clinical Investigation(s)

*State the primary and secondary objectives of the clinical trial, and state the duration of the proposed study, from the completed protocol.*

## Summary of Previous Human Experience

*This is a brief summary of previous human experience with the drug(s), with reference to the literature or other INDs if pertinent. Also, investigational or marketing experience in other countries may be relevant to the safety of the proposed clinical investigation(s). This topic will be written up in detail in Section 8. However, for many sponsor-investigator INDs that use commercially available drugs, Section 2.2 and 8 are often identical.*

## Status of Drug in Other Countries

*If the drug has been withdrawn from investigation or marketing in any country for any reason related to safety or effectiveness, identification of the country(ies) where the drug was withdrawn and the reasons for the withdrawal are stated here. For a Sponsor-Investigator IND, you may simply state you are not aware of any withdrawals.*

## References

*List any references for Section 2.*

# General Investigational Plan

## Rationale

*State here the rationale for the research study planned. Briefly refer to the non-clinical data supporting the rationale if relevant. The bulk of the non-clinical data (e.g., animal models, in vitro models, etc.) should be provided in the Pharmacology Section (Section 7). This section should be brief, one to two pages at most.*

## Indication(s) to be Studied

*This should be different from the indication the drug is already approved for.*

## General Approach for Evaluation of Treatment

*State here the sequence of studies planned or a general description of the population to be studied.*

## Description of First Year Trial(s)

*Briefly describe what kind of clinical study design you will use in the first year of the trial.*

### Number of Subjects to be Evaluated

## Drug Related Risks

*Any risks of particular severity or seriousness anticipated on the basis of the toxicological data in animals or prior studies in humans with the drug(s) or related drugs.*

## References

*List any references for Section 3.*

# Investigator Brochure

*For sponsor-investigator initiated INDs of approved products, there is no requirement to produce an Investigator Brochure. You can incorporate the following statement:*

In accordance with 21 CFR Part 312.55(a), an Investigator’s Brochure is not required for a sponsor-investigator IND.

*However, it is appropriate here to refer to the labeling and provide a URL link to the most current product label. You may find these links useful for finding current product labeling:*

* <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
* <http://www.accessdata.fda.gov/Scripts/cder/DrugsatFDA/>

*You may also reference Letters of Authorization in this section if you are receiving product directly from the manufacturer.*

# Protocol

## Study Protocol

*The complete clinical protocol for this clinical study can be included in the body of the IND or attached as an appendix to this IND, and referenced here* *as Appendix (x). Also, state here where the study is to take place and give the name and address of the Institutional Review Board responsible for the initial and continuing review and approval of the study.*

## Informed Consent

*If the investigation involves an exception from informed consent under 21 CFR 50.24, the sponsor shall prominently identify on Form FDA 1571 and here that the investigation is subject to the requirements in 21 CFR 50.24. Otherwise it must be stated here that informed consent will be obtained by the participants of the study in accordance with 21 CFR Part 50 Protection of Human Subjects.*

## Investigator and Facilities Data

*Attach FDA Form 1572 and CV of the principal investigator(s) as two appendixes, and reference those appendixes here. Actually, you are not required to submit form 1572 to the FDA. However, it is the easiest way to collect all the information that must be submitted under 21 CFR 312.23(a)(6)(iii)(b). The alternative is to submit the information as a narrative, but we highly recommend using the form.*

# Chemistry, Manufacturing and Control Information

*If the investigational drug has been marketed, this section may be covered by referring to the product labeling. You may refer back to the URL identified in Section 4. Alternatively, it might be appropriate to refer to a ‘Letter of Authorization’ referenced in Section 9 of Form FDA 1571 if using a drug provided by a commercial company.*

Dose Level

Lot Number

## Environmental Assessment

*Insert the statement below, unless there is a reason to believe the distribution and use of the drug could have an environmental impact.*

*“We request a claim for categorical exclusion for this proposed clinical trial as provided for in 21 CFR Part 312.31(e) in that the drug shipped under this notice is intended to be used in clinical trials in which the amount of waste expected to enter the environment may reasonably be expected to be non-toxic.”*

# Pharmacology and Toxicology Information

## Pharmacology and Drug Distribution

*This section should contain any non-clinical data supporting the rationale for the proposed study. This may be animal models of disease, cell-based models, or other supporting information. Depending on the importance of this information to your proposal you should consider how detailed the information should be. Always provide published literature supporting the claims.*

*If you are proposing a new route of administration for an approved drug be aware that FDA may require additional toxicology studies to be conducted. This should be discussed with FDA prior to submitting the IND.*

*As was true for Section 6, you may use an authorization letter(s) or cite the drug label to satisfy this section.*

# Previous Human Experience

*Provide a summary of known use of the product. If the drug(s) is already marketed in the US, then you may be able to simply refer to the product labeling. Some guidelines are listed below:*

1. *If the drug has been investigated or marketed previously, either in the United States or other countries, detailed information about such experience that is relevant to the safety of the proposed investigation or to the investigation’s rationale.*
2. *If the drug has been the subject of controlled trials that are not discussed in the product label, and are relevant to the proposed study, they should be summarized in this section. It is recommended to summarize the available clinical information in tabular form to ensure that reviewers can easily identify relevant studies. An example of a table format is provided below. Any published material that is relevant to the safety of the proposed investigation or to an assessment of the drug’s effectiveness for its proposed investigational use should be provided in full. Published material that is less directly relevant may be supplied by a bibliography.*
3. *If the drug is a combination of drugs previously investigated or marketed, the information should be provided for each active drug component. However, if any component in such combination is subject to an approved marketing application or is otherwise lawfully marketed in the United States, the sponsor is not required to submit published material concerning that active drug component unless such material relates directly to the proposed investigational use (including publications relevant to component- component interaction).*
4. *If the drug(s) has been marketed outside the United States, a list of the countries in which the drug has been marketed and a list of the countries in which the drug has been withdrawn from marketing for reasons potentially related to safety or effectiveness.*

**Table 1. Example of Data Summary Table**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Study  (Reference) | N (age range, years) | Treatment | Doses Administered | Outcome Measures | Reported Adverse Events  N (%) |
| Name (Bibliography) |  |  |  |  |  |
|  |  |  |  |  |  |

SD=Standard Deviation; SE=Standard Error

## References

*List any references for Section 8.*

# AdDitional Information

*In certain applications, as described below, information on special topics may be needed. Such information shall be submitted in this section as outlined below. Otherwise you may simply state ‘not applicable’. This could include specific information requested by FDA following a pre-IND meeting.*

## Drug Dependence and Abuse Potential

*If the drug is a psychotropic substance or otherwise has abuse potential, a section describing relevant clinical studies and experience and studies in test animals.*

## Radioactive Drugs

*If the drug is a radioactive drug, sufficient data from animal or human studies should be provided, to allow a reasonable calculation of radiation-absorbed dose to the whole body and critical organs upon administration to a human subject. Phase 1 studies of radioactive drugs must include studies which will obtain sufficient data for dosimetry calculations.*

## Pediatric Studies

*If the investigational drug will be studied in pediatric setting, plans for assessing pediatric safety and effectiveness should be provided.*

## Other Information

*A brief statement of any other information that would aid evaluation of the proposed clinical investigations with respect to their safety or their design and potential as controlled clinical trials to support marketing of the drug.*

## Selected References

*If you are including reprints with your submission, list them in this section.*

# Relevant Information

*If requested by FDA, any other relevant information needed for review of the application.*