

Information and guidance sheet for the completion of the Investigational New Drug Application (IND). (Form FDA 1571).

Purpose

An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. The authorization must be secured prior to shipment and administration of any new drug that is not the subject of an approved new drug application. The initial IND submission and each subsequent submission to the IND must be accompanied by Form FDA 1571.

Important notes

- All information presented in this information and guidance sheet is as a supplement to the FDA guidance titled “**Instructions for filling out Form FDA 1571-Investigational New Drug Application (IND)**”. It is recommended to read those instructions alongside this information and guidance sheet.
- The current version of the form and instructions can be located at:
 - <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>

This is the link to access all FDA forms. Once you have accessed the link, scroll down to the "1571" noted in the forms column to ensure use of the most current form and instruction sheet. In the instance when the FDA's Office of Management and Budget (OMB) has not posted an updated Form FDA 1571 and the expired version is the only one available on the website, it is acceptable to use the expired form.

Who is responsible for the completion of the Form FDA 1571?

- The Sponsor is responsible for initiating and signing Form FDA 1571.
 - The sponsor is the person who takes responsibility for and initiates a clinical investigation.
 - The sponsor may be an individual, pharmaceutical company, governmental agency, academic institution, private organization or other organization (21 CFR 312.3(b)).
 - **NOTE:** If a pharmaceutical company will be supplying the drug, but will not itself be submitting the IND, the pharmaceutical company is not the sponsor.
- A Sponsor-Investigator is an individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug is being administered or dispensed (21 CFR 312.3(b)).
 - For a Sponsor-Investigator IND, Items 2 – 4 listed in the Form field #13 may be briefly addressed in the cover letter or in a summary.
 - Copies of Form FDA 1572 (with its attachments) may be sent by the Sponsor-Investigator to FDA to satisfy Form FDA 1571, box 12, item 6 b-d. Information can be supplied in the form of attachments (such as curriculum vitae) rather than entering that information directly onto the form, but this should be so noted under the relevant section numbers.
- If the person signing the application (Field 25) does not reside/have place of business within the United States, the submission must be countersigned by an attorney/agent/authorized official who resides/has a place of business within the United States.
- For administrative reasons, only one individual should be designated as sponsor.

Completion of the Form FDA 1571.

- Sponsors should complete the form, but not modify the security settings or make other changes to the form since the approved, secured, posted form has been tested and allows for automated processing of submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).
- There is no need to prepare and sign a new Form FDA 1571 when the OMB expiration date has been reached.
- Ensure that all information is present and correct.
- Ensure that the application number is present and correct.
- Verify all of the information submitted is consistent with information written in Form FDA 1571.
- Provide the IND number if it was previously assigned. If an IND number has not been assigned, leave the field blank.
- For IND numbers less than six digits, the IND number should be preceded using zeros (i.e., for IND 12345 enter 012345).
- For name(s) of drug (21 CFR 312.23(a)(1)(i)), list the generic name(s) and trade name, if available.
- Provide the dosage form, the unique ingredient identifier (UNII) term and code for active substances (if applicable).
- Use the Continuation Page if additional space is needed.
- If any sponsor obligations will be transferred to a CRO then this should be included in Field 14 of the Form FDA 1571. A Continuation Page should be used to provide a statement containing the name and address of the CRO, identification of the clinical study and a listing of the obligations transferred (21 CFR 312.23(a)(1)(viii)).

Making corrections to the Form FDA 1571.

- Hand corrections to the Form FDA 1571 may be made by crossing out incorrect information with a single line, signing and dating the error by the Sponsor-Investigator. Corrections to typographical errors using correction fluid (e.g. "white out") and/or correction tape are not allowed.

Sending the application - submitting a paper version.

- The initial IND submission and each subsequent submission to the IND should be accompanied by Form FDA 1571.
- The form should be submitted in triplicate, (one original and two copies).
- Mailing addresses for Initial submissions:

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| <p>For a Drug: Food and Drug Administration Center for Drug Evaluation and Research Central Document Room 5901-B Ammendale Rd. Beltsville, Md. 20705-1266</p> | <p>For a Therapeutic Biological Product: Food and Drug Administration Center for Drug Evaluation and Research Therapeutic Biological Products Document Room 5901-B Ammendale Road Beltsville, MD 20705-1266</p> |
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END OF INFORMATION AND GUIDANCE SHEET