



INFORMATION FOR SPONSOR-INVESTIGATORS SUBMITTING INVESTIGATIONAL NEW DRUG APPLICATIONS (INDs)

An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug that is not the subject of an approved new drug application.

IND regulations are contained in Title 21, Code of Federal Regulations, Part 312. Copies of the regulations, further guidance regarding IND procedures, and additional forms are available from the FDA Center for Drug Evaluation and Research, Drug Information Branch (HFD-210), 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 827-4573 or toll free at 1-888-INFOFDA. In addition, forms, regulations, guidances, and a wide variety of additional information is available online at <http://www.fda.gov/cder/>. Forms may be accessed directly at either <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html> or <http://forms.psc.gov/forms/FDA/fda.html>

The following instructions address only the administrative aspects of preparing and submitting an IND, and are intended primarily to provide assistance to individual Sponsor-Investigator applicants, not pharmaceutical companies.

WHERE TO SEND THE APPLICATION:

The initial IND submission and each subsequent submission to the IND should be accompanied by a Form FDA 1571 and must be submitted in triplicate (the original and two photocopies are acceptable). Mailing addresses for initial IND submissions are:

For a Drug:

Food and Drug Administration
Center for Drug Evaluation and
Research
Central Document Room
12229 Wilkins Ave.
Rockville, MD 20852-1833

For a Biologic:

Food and Drug Administration
Center for Biologics Evaluation
and Research, HFM-99, Rm 200N
1401 Rockville Pike
Rockville, MD 20852-1448

FILLING OUT THE FORM FDA 1571: (The numbers below correspond to the numbered boxes on the Form FDA 1571.)

1. The sponsor is the person who takes responsibility for and initiates a clinical investigation. The sponsor may be a pharmaceutical company, a private or academic organization, or an individual. **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. For administrative reasons, only one individual should be designated as sponsor.

If a pharmaceutical company will be supplying the drug, but will not itself be submitting the IND, the company is not the sponsor.

2. The date of submission is the date that the application is mailed to FDA.
3. The address is the address to which written correspondence from FDA should be directed. If this address is a post office box number, a street address must also be provided.
4. The telephone number is the number where the sponsor is usually available during normal working hours. A telephone number must be provided.
5. For name(s) of drug, list the generic name(s) and trade name, if available. Also, state the dosage form(s).
6. If an emergency IND number was previously assigned by FDA, or the Form FDA 1571 is being included with an amendment to the original IND, then that IND number should be entered here; otherwise, the space should be left blank.
7. Self-explanatory.
8. This section is to be completed by pharmaceutical firms that are conducting clinical studies in support of a marketing application. Sponsor-Investigators need not complete this section.
9. It is necessary for the sponsor to submit certain information with an IND (such as manufacturing and controls information, pharmacology and toxicology data, or data from prior human studies) unless that information has previously been submitted to FDA, AND the sponsor of the previously submitted information provides a letter authorizing FDA to refer to the information. In this case, the letter of authorization including the file identification (IND/DMF/NDA number) must be: 1) submitted to the authorizer's application and, 2) included in the initial submission of the new sponsor's IND. The sole exception to this requirement is when a marketed drug is used in the study, without modification to its approved packaging, in which case the marketed drug product must be identified by trade name, established name, dosage form, strength, and lot number.
10. Numbering of submissions is primarily intended for pharmaceutical firms. Sponsor-Investigators do not have to complete this section.
11. For an original IND submission, only the "Initial Investigational New Drug Application (IND)" box should be checked. For subsequent submissions, check ALL the boxes that apply since the submission may contain more than one type of information.

Requests to charge and Treatment Protocols must be submitted separately. Treatment INDs and Treatment Protocols are special cases and are not intended

for single patient use. Before checking either of these boxes, the sponsor should be thoroughly familiar with the cited regulations and contact the appropriate FDA reviewing division to discuss the proposed treatment use.

12. For a Sponsor-Investigator IND, items 2, 3, and 4 may be briefly addressed in the cover letter or in a summary.

Where the investigational drug is obtained from a supplier in a final dosage form, items 5, 7, 8, and 9 may be referenced if authorization is given by the supplier (see explanation in section 9 above). If the investigational drug is prepared or altered in any way after shipment by the supplier, complete manufacturing (or compounding) and controls information, including information on sterility and pyrogenicity testing for parenteral drugs, must be submitted for that process in Item 7.

Item 6 requires that the protocol be submitted, along with information on the investigators, facilities, and Institutional Review Board (copies of the completed Form FDA 1572 with attachments would suffice for 6 b-d).

Item 7 also requires submission of either a claim of categorical exclusion from the requirement to submit an environmental assessment or an environmental assessment (21 CFR 25.15[a]). When claiming a categorical exclusion, the sponsor should include the following statements: "I claim categorical exclusion (under 21 CFR 25.31[e]) for the study(ies) under this IND. To my knowledge, no extraordinary circumstances exist."

13. This section does not pertain to a Sponsor-Investigator.

14-15. For a pharmaceutical firm, the name of the person responsible for monitoring the conduct of the clinical investigation, and reviewing and evaluating safety information, should be entered. For Sponsor-Investigator INDs, the investigator has this responsibility.

N.B. Certain important commitments that the IND sponsor makes by signing the form FDA 1571 are listed below box 15.

16-17. For an IND sponsored by a pharmaceutical firm or research organization, the name of the sponsor's authorizing representative would be entered and that individual must sign the form. For a Sponsor-Investigator IND, the Sponsor-Investigator should be named and must sign the form.

18-19. Box 18 and 19 need not be completed if they duplicate boxes 3 and 4.

20. The date here is the date the form is signed by the sponsor.

FORM FDA 1572:

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 a curriculum vitae) rather than entering that information

directly onto the form, but this should be so noted under the relevant section numbers.

FDA RECEIPT OF THE IND:

Upon receipt of the IND by FDA, an IND number will be assigned, and the application will be forwarded to the appropriate reviewing division. The reviewing division will send a letter to the Sponsor-Investigator providing notification of the IND number assigned, date of receipt of the original application, address where future submissions to the IND should be sent, and the name and telephone number of the FDA person to whom questions about the application should be directed. Studies shall not be initiated until 30 days after the date of receipt of the IND by FDA unless you receive earlier notification by FDA that studies may begin.

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Center for Drug Evaluation and Research

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