Center responsible for regulating the product as follows:

(1) For drug products regulated by CDER. Send the IND submission to the Central Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 5901-B Ammendale Rd., Beltsville, MD 20705-1266; except send an IND submission for an in vivo bioavailability or bioequivalence study in humans to support an abbreviated new drug application to the Office of Generic Drugs (HFD–600), Center for Drug Evaluation and Research, Food and Drug Administration, Metro Park North VII, 7620 Standish Pl., Rockville, MD 20855.

(2) For biological products regulated by CDER. Send the IND submission to the CDER Therapeutic Biological Products Document Room, Center for Drug Evaluation and Research, Food and Drug Administration, 12229 Wilkins Ave., Rockville, MD 20852.

(3) For biological products regulated by CBER. Send the IND submission to the Document Control Center (HFM–90), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448.

(b) On receiving the IND, the responsible Center will inform the sponsor which one of the divisions in CDER or CBER is responsible for the IND. Amendments, reports, and other correspondence relating to matters covered by the IND should be sent to the appropriate center at the address indicated in this section and marked to the attention of the responsible division. The outside wrapper of each submission shall state what is contained in the submission, for example, “IND Application”, “Protocol Amendment”, etc.

(c) All correspondence relating to export of an investigational drug under §312.110(b)(2) shall be submitted to the International Affairs Staff (HFY–50), Office of Health Affairs, Food and Drug Administration, 5000 Fishters Lane, Rockville, MD 20857.

Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests

§312.160 Drugs for investigational use in laboratory research animals or in vitro tests.

(a) Authorization to ship. (1)(i) A person may ship a drug intended solely for tests in vitro or in animals used only for laboratory research purposes if it is labeled as follows:

CAUTION: Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans.

(ii) A person may ship a biological product for investigational in vitro diagnostic use that is listed in §312.2(b)(2)(ii) if it is labeled as follows:

CAUTION: Contains a biological product for investigational in vitro diagnostic tests only.

(b) A person shipping a drug under paragraph (a) of this section shall use
due diligence to assure that the con-
signee is regularly engaged in con-
ducting such tests and that the ship-
ment of the new drug will actually be
used for tests in vitro or in animals
used only for laboratory research.

(3) A person who ships a drug under
paragraph (a) of this section shall
maintain adequate records showing the
name and post office address of the ex-
pert to whom the drug is shipped and
the date, quantity, and batch or code
mark of each shipment and delivery.
Records of shipments under paragraph
(a)(1)(i) of this section are to be main-
tained for a period of 2 years after the
shipment. Records and reports of data
and shipments under paragraph
(a)(1)(ii) of this section are to be main-
tained in accordance with §312.57(b).
The person who ships the drug shall
upon request from any properly au-
thorized officer or employee of the
Food and Drug Administration, at rea-
sonable times, permit such officer or
employee to have access to and copy
and verify records required to be main-
tained under this section.

(b) Termination of authorization to
ship. FDA may terminate authoriza-
tion to ship a drug under this section if
it finds that:

(1) The sponsor of the investigation
has failed to comply with any of the
conditions for shipment established
under this section; or

(2) The continuance of the investiga-
tion is unsafe or otherwise contrary to
the public interest or the drug is used
for purposes other than bona fide sci-
centific investigation. FDA will notify
the person shipping the drug of its find-
ing and invite immediate correction. If
correction is not immediately made,
the person shall have an opportunity
for a regulatory hearing before FDA
pursuant to part 16.

(c) Disposition of unused drug. The
person who ships the drug under para-
graph (a) of this section shall assure
the return of all unused supplies of the
drug from individual investigators
whenever the investigation discon-
tinues or the investigation is termi-
nated. The person who ships the drug
may authorize in writing alternative
disposition of unused supplies of the
drug provided this alternative disposi-
tion does not expose humans to risks
from the drug, either directly or indi-
rectly (e.g., through food-producing
animals). The shipper shall maintain
records of any alternative disposition.

[52 FR 8831, Mar. 19, 1987, as amended at 52
FR 23031, June 17, 1987. Redesignated at 53
FR 41523, Oct. 21, 1988; 67 FR 9586, Mar. 4,
2002]

Subpart H [Reserved]

Subpart I—Expanded Access to
Investigational Drugs for Treat-
ment Use

SOURCE: 74 FR 40942, Aug. 13, 2009, unless
otherwise noted.

§ 312.300 General.

(a) Scope. This subpart contains the
requirements for the use of investiga-
tional new drugs and approved drugs
where availability is limited by a risk
evaluation and mitigation strategy
(REMS) when the primary purpose is to
diagnose, monitor, or treat a patient’s
disease or condition. The aim of this
subpart is to facilitate the availability
of such drugs to patients with serious
diseases or conditions when there is no
comparable or satisfactory alternative
therapy to diagnose, monitor, or treat
the patient’s disease or condition.

(b) Definitions. The following defini-
tions of terms apply to this subpart:

Immediately life-threatening disease or
condition means a stage of disease in
which there is reasonable likelihood
that death will occur within a matter
of months or in which premature death
is likely without early treatment.

Serious disease or condition means a
disease or condition associated with
morbidity that has substantial impact
on day-to-day functioning. Short-lived
and self-limiting morbidity will usu-
ally not be sufficient, but the mor-
bidity need not be irreversible, pro-
vided it is persistent or recurrent.
Whether a disease or condition is seri-
ous is a matter of clinical judgment,
based on its impact on such factors as
survival, day-to-day functioning, or the
likelihood that the disease, if left un-
treated, will progress from a less severe
condition to a more serious one.