The term “drug product” references investigational and approved drugs (including radioisotopes), biological products, and dietary supplements. For each drug product used for this research, add product labeling, package insert, Investigator Brochure and clinical protocol (as applicable).

Submit a copy of all FDA or sponsor documents related to this drug including Investigational New Drug (IND) documentation.

In the protocol, address the risks associated with the use of the drug and how those risks will be minimized. Note that the FDA considers ephedra alkaloids to pose a significant and unreasonable risk and research involving these drugs must be justified. Include in the protocol and consent form (or other document as appropriate) how participants will be instructed in the use of the drug product. If the drug is a radioisotope, add approval from institutional radiation committee. If the drug is considered a biological product, add approval from institutional biosafety committee. Drug products to be used solely *in vitro*, must comply with shipping labels requirements (see [21 CFR 312.160](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.160)). The PI must adhere to requirements at [21 CFR 312 Subpart D](https://www.ecfr.gov/cgi-bin/text-idx?SID=bdfb34d8d268dffa9872f782a2e42758&mc=true&node=sp21.5.312.d&rgn=div6).

1. Drug information.

Drug name:

Drug manufacturer:

Product formulation:

Dose and strength:

Route of administration:

Is the drug a controlled substance? Note: drugs subject to the Controlled Substances Act must be stored in a securely locked, substantially constructed cabinet or enclosure.

Yes, classification:

No.

Is the drug investigational or FDA approved?

Investigational

FDA approved

1. Describe the procedures for dispensing the drug including who will dispense and how it will be dispensed. If someone other than the PI or a pharmacist is dispensing the drug, describe how the PI will train and evaluate to ensure that it is provided as required for the research:
2. Describe where the drug will be stored and how it will be secured (including limited access):
3. Specify who is prescribing the drug, including contact information:
4. Describe the plan for unused drug including skipped doses as well as following discontinuation, termination, suspension, or completion of the investigation:
5. Does the drug have an IND?  Yes  No
6. Are you requesting an IND exemption?

Yes. Answer the following questions.

No. Skip the following questions.

*Indicate whether the following apply to the research:*

The drug is FDA Approved and lawfully marketed in the United States.

True  False

The research is not intended to be reported to the FDA as a well-controlled project in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.

True  False

The research is not intended to support a significant change in the advertising for the product.

True  False

The research does not involve a route of administration or dosage level or use in a patient population or other factor (e.g. population) that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug.

True  False

The research will be conducted in compliance with the FDA requirements for promotion and charging for investigational drugs (21 CFR 312.7); researchers and sponsors may not promote investigational new drugs as being safe and effective and they may not charge for, distribute, or test these drugs without FDA approval.

True  False