|  |  |
| --- | --- |
| **Study Title** |       |
| **PI Name** |       |

**Complete the appropriate section: either Drugs & Biologics or Supplements & Botanicals.**

**If your research involves more than one item, fill out a separate supplement for each item.**

**Useful Guidance**:

FDA Guidance “Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND”, September 2013, available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf>

This guidance describes how to obtain consultation from the FDA about whether an IND is required. It also includes guidance about when an IND is required for studies involving:

* Use of endogenous compounds
* Administration of live organisms (e.g., modified or wild-type virus) to subjects
* Dietary supplements, complementary or alternative medicines including organic materials from botanical sources

**Definitions**:

**IND** – Investigational New Drug Application

**Drug** – An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or an article (other than food) intended to affect the structure or any function of the body of man or other animals. (Note, however, that (1) a dietary supplement intended only to affect the structure or function of the body and not intended for a therapeutic purpose is not a drug and (2) a food used as such (i.e., primarily for its taste, aroma, or nutritive value) and not for a therapeutic purpose or to affect the structure or function of the body, other than by providing nutrition, is not a drug.)

**Biologics** – a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. (Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies.)

**Dietary supplement** – product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements can be found in many forms such as tablets, capsules, softgels, liquids, or powders.

 **DRUGS & BIOLOGICS**

For Drugs & Biologics, the following information must be submitted:

* Package Insert or Investigator’s Brochure
* If the study involves an IND: (one of the following)
	+ Written communication from the FDA documenting the IND number
	+ Sponsor protocol imprinted with the IND number
	+ Written communication from the sponsor documenting the IND number

|  |  |
| --- | --- |
| **1a.** | Generic name:       |
| Brand name (if applicable):       |
| Dose(s) and dosage form(s) to be used in this study:       |
| Frequency and route of administration to be used in this study:       |
|  |
| **1b.** | Check the applicable category below: (choose one) |
| [ ]  | The drug or biologic is approved for the indication for which it is being used in this research |
| [ ]  | The drug or biologic has a valid IND.IND#:      Holder of the IND:       |
| [ ]  | The drug or biologic is exempt from the IND requirements. For research involving marketed drug products, ALL of the criteria below must be met:* The drug is lawfully marketed in the United States.
* The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.
* In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug.
* The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product.
* The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50).
* The investigation is conducted in compliance with the requirements of § 312.7 (i.e., the investigation is not intended to promote or commercialize the drug product).
 |
| For help in determining whether the investigation is exempt from IND requirements, please contact the Office of Research Compliance. |
| For bioavailability or bioequivalence (BA/BE) studies or research involving radioactive isotopes or cold isotopes, please contact the Office of Research Compliance. |
|  |
| **1c.** | How are you obtaining the item?[ ]  Commercial manufacturer (such as a drug company)[ ]  Prescription[ ]  Direct purchase (such as from a drug store)[ ]  Research lab[ ]  Compounding pharmacy[ ]  Other. Explain:       |
|  |
| **1d.** | Indicate the phase of the investigation:  |
| [ ]  Phase I  | [ ]  Phase II/III |
| [ ]  Phase I/II  | [ ]  Phase III |
| [ ]  Phase II | [ ]  Phase IV |
|  |
| **1e.** | Is preparation or repackaging of the supplied product necessary before administration or dispensing? | [ ]  Yes [ ]  No |
| **If yes,** state who will perform these activities and where they will be performed.      |

**SUPPLEMENTS & BOTANICALS**

|  |  |
| --- | --- |
| **2a.** | Generic name:       |
| Brand name (if applicable):       |
| Dose(s) and dosage form(s) to be used in this study:       |
| Frequency and route of administration to be used in this study:       |
|  |
| **2b.** | Identify the source(s)/manufacturer(s):      |
|  |
| **2c.** | Is the supplement or botanical sold over-the-counter in the U.S.?“Over-the-counter” means that the dietary supplement(s) is sold in stores in the U.S. or online if the online seller is physically located in the U.S. | [ ]  Yes [ ]  No |
| **If no,** you must include a third-party certificate of analysis from one of the following sources: Consumerlab.com; NSF International; or USP.  |
|  |
| **2d.** | Identify the intent of the research evaluation:[ ]  To evaluate the item’s ability to diagnose, cure, mitigate, treat, or prevent a disease or  Condition (If checked, an IND is required.)[ ]  To study the relationship between an item’s effect on normal structure or function in humans (e.g., guarana and maximal oxygen uptake)[ ]  To characterize the mechanism by which an item acts to maintain a normal structure or  function in humans (e.g., fiber and bowel regularity)[ ]  Other. Explain:       |