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

**DRUGS & BIOLOGICS**

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

* Package insert or comparable

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| --- | --- |
| **1a.** | Generic name: |
| Brand name: |
| Dose(s): |
| Frequency and route of administration: |
|  | |
|  | |
| **1b.** | 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. Please explain: |
|  | |

**SUPPLEMENTS & BOTANICALS**

For Supplements & Botanicals, the following information must be submitted:

* Package insert or comparable

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| --- | --- | --- |
| **2a.** | Generic name: | |
| Brand name (if applicable): | |
| Dose(s): | |
| Frequency and route of administration: | |
|  | | |
| **2b.** | Identify the source(s)/manufacturer(s), including contact information: | |
|  | | |
| **2c.** | Does the supplement or botanical meet the standards for current Good Manufacturing Practice (GMP)? | ☐ Yes ☐ No |
| **If yes,** submit documentation.  **If no,** please explain: | |
|  | | |
| **2d.** | What effort are the investigators making to ensure the quality and safety of the supplement/botanical? | |

**Describe the safety of both the dosage and the drug/biologic/supplement/botanical. What efforts are you making to reduce risk to participants in regard to the drug/biologic/supplement/botanical?**