1. Quality assurance/quality control from the manufacturer
   1. Manufacturer information: name, address
   2. Manufacturing procedure: process following cGMP, GLP, and DSHEA recommendations
   3. Certificate of analysis, quality assurance, quality control, and consistency of product
   4. Confirmation that study products will be from single, identifiable batch
2. IND, NDA, GRAS status, notification letters, other status with the FDA, or other government agencies if applicable. Submit copies of all documents.
3. Ingredient information
   1. Detailed ingredient list and specific amounts and dosages: active and inactive
   2. Detailed information on each ingredient, literature reviews, monographs, references, etc.
4. Toxicology and/or pharmacology profile
   1. Review of literature
5. Pharmacodynamics, pharmacokinetics, and bioavailability
   1. Mechanism of action
   2. Potential/hypothesis of mechanism of action
6. Protocol: dose frequency, length of treatment, timeline, special instructions
7. Current outcomes data/field report and/or anticipated outcomes
   1. Anticipated objective outcomes
8. Clinical effects
   1. Anticipated subjective outcomes
      1. Physical
      2. Biochemical, physiological, structural, etc.
   2. Physical, emotional, mental, behavioral, etc. if applicable
9. Adverse events, risks, drug interactions, toxicity, precautions, contraindications, special instructions. Include findings from:
   1. Field reports
   2. Published reports: preclinical (animal), in vitro, in vivo, clinical studies
   3. Adverse events anticipated
   4. Adverse events in theory
10. Intervention products
    1. Final product samples must be sent to PI prior to distribution of any products
    2. Extra products must be provided for each study group (5-10% of study products)
    3. Individual codes sealed in envelopes per study subject plus one master code must be provided
    4. Product label should include code, batch number, expiration date, and dose instructions and emergency call #.