# Dietary Supplement Checklist

This checklist may be used by investigators to determine whether a dietary supplement, defined as a product (other than tobacco) intended to supplement the diet that bears or contains one or more dietary ingredients, is subject to FDA regulation.[i]

**Please complete the form and attach to your initial study application.**

**Principal Investigator:**

**Title of Study:**

| Yes | No | Mark "Yes" or "No" for each of the statements below. |
|---|---|---|
| ☐ | ☐ | Is the product used in this study a lawfully marketed botanical dietary supplement being studied for its effects on diseases in the proposed investigation (i.e., to cure, treat, mitigate, prevent, or diagnose disease[ii] including its associated symptoms)? If yes, an IND is required under part 312. |
| ☐ | ☐ | Is the clinical investigation designed to make a disease claim,[iii] a nutrient content or a health claim? If yes, an IND is required under part 312. |
| ☐ | ☐ | Is the product used in this study a lawfully marketed botanical dietary supplement being studied for its dietary supplement use (i.e., structure and/or function claims)? If no, an IND is not required. |
| ☐ | ☐ | Is the clinical investigation designed to study the relationship between the dietary supplement's effect on normal structure or function in humans or to characterize the mechanism by which a dietary supplement acts to maintain such structure or function? If yes, an IND is not required. |

---

i Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), a dietary supplement is defined, as "a product (other than tobacco) intended to supplement the diet that bears or 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 are taken by mouth and can be found in many forms such as tablets, capsules, soft gels, liquids, gel caps, or powders. Dietary supplements can also take other forms, such as a bar. Under DSHEA, a dietary supplement is not considered a drug and is not subject to the premarket approval requirements for drugs if the intended use for which it is marketed is only to affect the structure or any function of the body and not intended to be used for a therapeutic purpose. Therefore, whether an IND is needed for a clinical investigation evaluating a dietary supplement is determined by the intent of the clinical investigation. If the clinical investigation is intended only to evaluate the dietary supplement's effect on the structure or function of the body, an IND is not required. However, if the clinical investigation is intended to evaluate the dietary supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease, an IND is required under part 312.

ii Disease" is defined as damage to an organ, part, structure, or system of the body such that the organ, part, structure, or system does not function properly (e.g., cardiovascular disease) or a state of health leading to such dysfunction (e.g., hypertension).

iii Has an effect on a specific disease or class of diseases; Has an effect on the characteristic signs or symptoms of a specific disease or classic diseases; Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm; Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases; Is a substitute for a product that is a therapy for a disease; Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases; Has a role in the body's response to a disease or to a vector of a disease; Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or Otherwise suggests an effect on a disease or diseases.