Is an Investigational New Drug (IND) Application Required?

Note: Studies involving drugs but exempt from IND requirements still are subject to other FDA regulations including 21 CFR part 50 (human subjects protections), part 54 (conflict of interest requirements), and part 56 (IRB requirements).

A product that is (i) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and acts through metabolism, chemical reactions, or the like; (ii) recognized in the US Pharmacopeia, official Homeopathic Pharmacopia, National Formulary; (iii) intended to affect the structure or function of the body and acts through metabolism, chemical reactions, or the like; or (iv) a component of any of the above is a drug.

Foods and dietary supplements generally are not regulated as drugs. However, those that are intended or promoted to be used in the diagnosis, cure mitigation, treatment, or prevention of disease are considered drugs.

If the product (i) is blood grouping serum, reagent red blood cells, or anti-human globulin; and (ii) is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure, it is exempt from IND requirements as long as it is shipped with special labeling requirements. See 21 C.F.R. § 312.160.

- The investigation is not intended to be reported to FDA as a well-controlled study 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;
- If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
- The investigation is conducted in compliance with the requirements of 312.7.

Note: If the study involves the use of a placebo and is otherwise exempt, it does not require an IND.