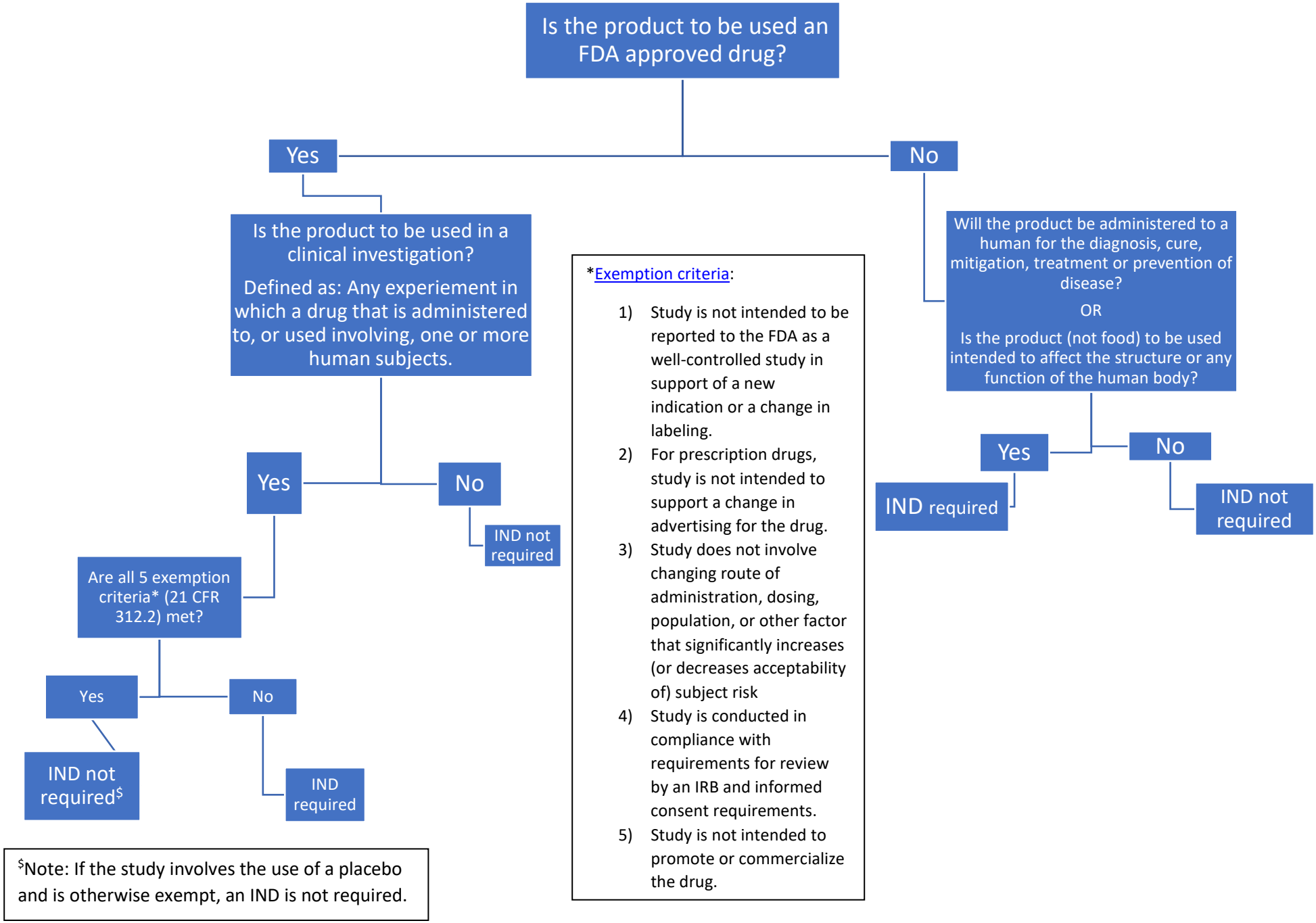
Is the product to be used an FDA approved drug?
Yes
No
Is the product to be used in a clinical investigation?
Defined as: Any experiement in which a drug that is administered to, or used involving, one or more human subjects.
Yes
No
IND not required
Are all 5 exemption criteria* (21 CFR 312.2) met?
Yes
No
IND not required$
IND required
Will the product be administered to a human for the diagnosis, cure, mitigation, treatment or prevention of disease?
OR
Is the product (not food) to be used intended to affect the structure or any function of the human body?
Yes
No
IND required
IND not required
*Exemption criteria:
1) Study is not intended to be reported to the FDA as a well-controlled study in support of a new indication or a change in labeling.
2) For prescription drugs, study is not intended to support a change in advertising for the drug.
3) Study does not involve changing route of administration, dosing, population, or other factor that significantly increases (or decreases acceptability of) subject risk
4) Study is conducted in compliance with requirements for review by an IRB and informed consent requirements.
5) Study is not intended to promote or commercialize the drug.
$Note: If the study involves the use of a placebo and is otherwise exempt, an IND is not required.

Definitions:

- **Clinical Investigation** - Definition per 21 CFR 312: Any experiment in which a drug (whether approved or unapproved) that is administered to, or used involving, one or more human subjects. An experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
- **Drug** - Definition per section 201(g)(1) of the Food, Drug, and Cosmetic Act includes, among other things: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease…" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals"
- **Investigational Drug** – An article that is not approved (for marketing) in the US as a drug AND an *approved* drug that is not used according to the approved label (or used in a new combination of approved drugs)
- **Practice of Medicine** – Allows a physician to use any approved drug for any reason without prior regulatory approval

Relevant FDA Guidances:

- IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ind-exemptions-studies-lawfully-marketed-drug-or-biological-products-treatment-cancer
- Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-inds-determining-whether-human-research-studies-can-be