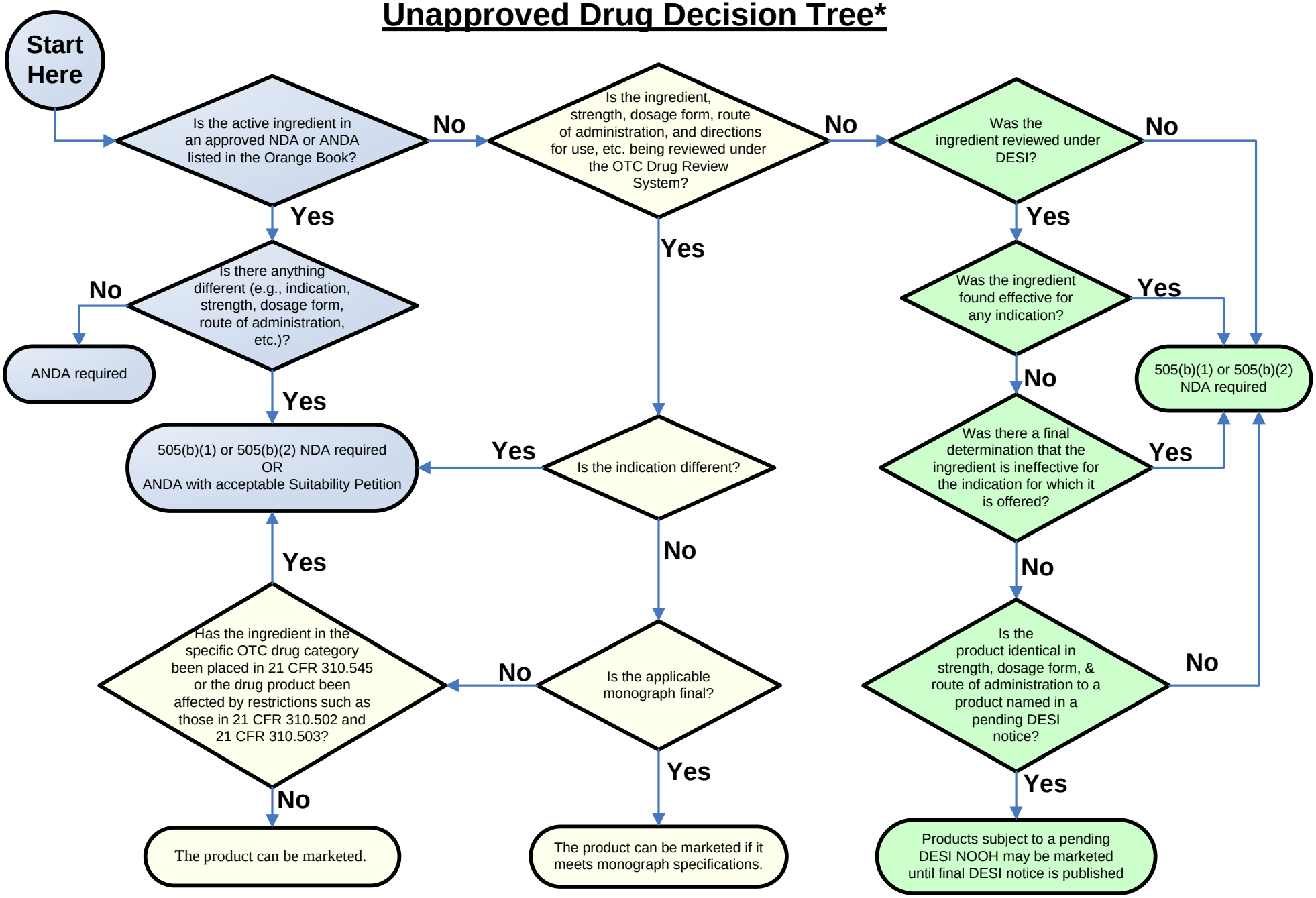
Unapproved Drug Decision Tree*



*** While this decision tree provides an overall approach to understanding how marketed unapproved drugs may comply with requirements under the FDCA under current policies, as applied to any particular drug product there may be variations and additional relevant factors. For instance, when a drug contains more than one active ingredient, each ingredient, as well as the combination as a whole, will need to be addressed. In addition, when an ingredient has been reviewed in more than one DESI proceeding, the Agency will apply the regulation at 21 CFR 310.6 to determine which proceeding applies to a particular drug product.**