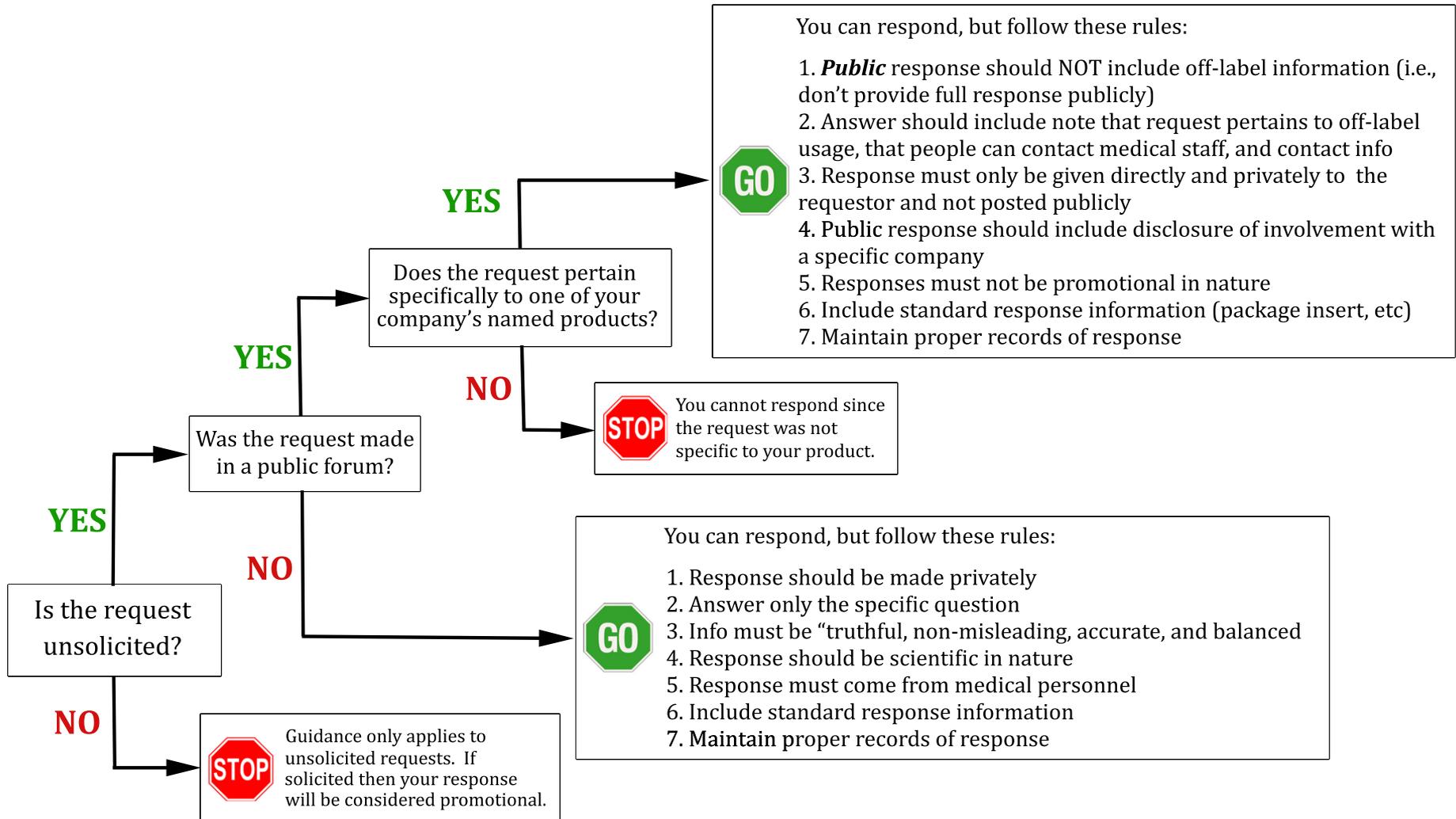


Responding to Requests for Off-Label Information

FDA Draft Guidance Translator



Definitions:

Unsolicited: requests that are initiated by people that are "completely independent of the relevant firm"

Public: request made in public forum, "whether directed to a specific firm or to a forum at large." (Example: post on third-party website forum, question at live presentation)

Non-public: "request that is directed privately to a firm using a one-to-one communication approach." (Example: phone call or email to medical information staff at company)

Named Product: Request about a specific product versus general question. (Example: "Can Drug X be used for..." is "named" and specific, "What drug works well for condition Y..." is not)