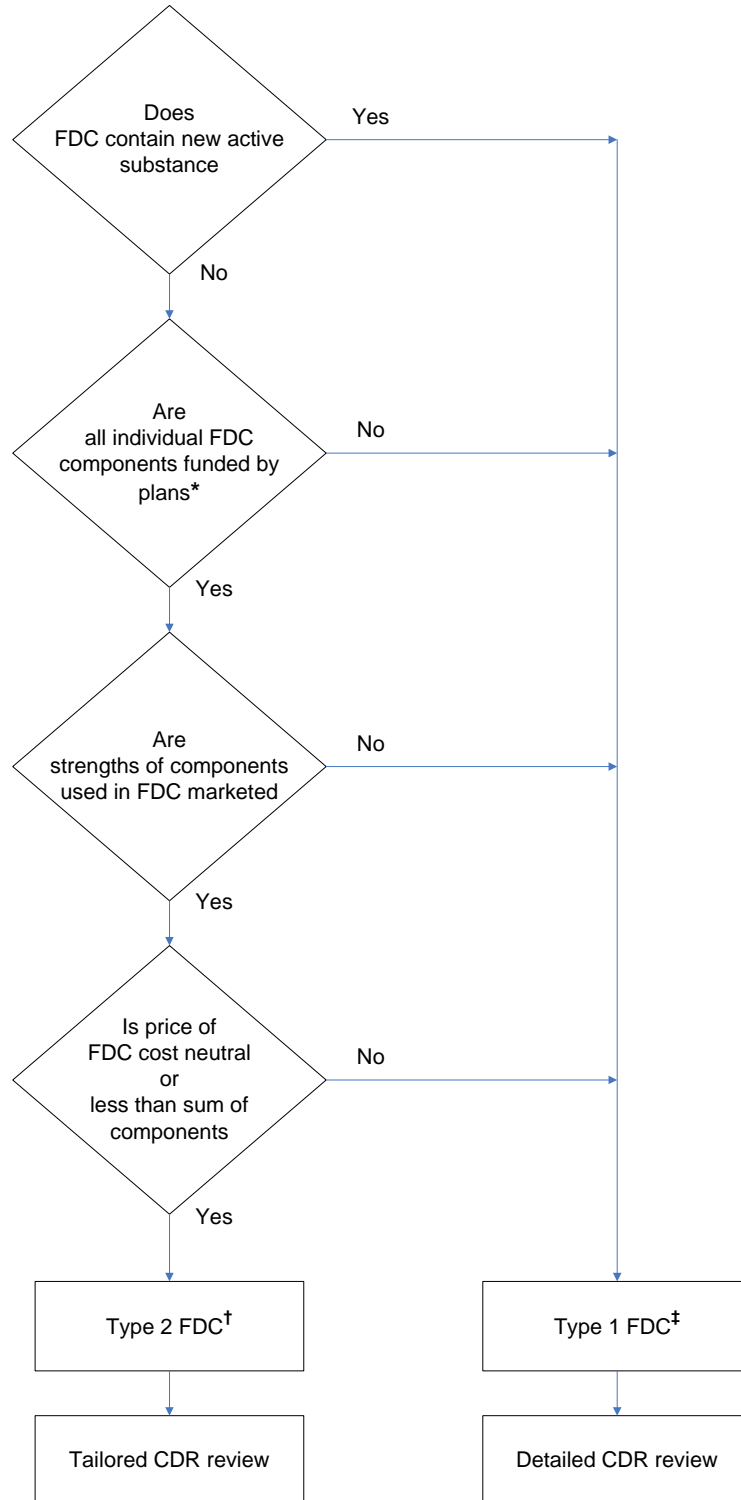


Flowchart for Determining what Type of Review and Submission is Required for Fixed Dose Combinations



CDR = Common Drug Review
FDC = Fixed Dose Combination

* If there are questions about whether a FDC submission should proceed to CDR or whether it requires a detailed or tailored review, input or direction will be sought from Advisory Committee on Pharmaceuticals (ACP).

† Type 2 FDC = fixed dose combination containing two or more drugs already funded by the participating drug plans. The FDC may contain non-prescription drugs funded by the drug plans, but at least one other component must be a prescription drug.

‡ Type 1 FDC = all other types of fixed dose combination products.