

CODE AND THERAPEUTIC DEFINITIONS

“A” codes are drug products that are considered by the FDA to be therapeutically equivalent to other pharmaceutically equivalent products.

- AA** Products not presenting bioequivalence problems in conventional dosage forms.
- AB** Products meeting necessary bioequivalence requirements.
- AP** Injectable aqueous solutions.
- AT** Topical products that are considered therapeutically equivalent to other pharmaceutically equivalent products.
- AO** Injectable oil solutions that are considered therapeutically equivalent to other pharmaceutically equivalent products.

“B” codes are drug products that the FDA does not at this time consider to be therapeutically equivalent to other pharmaceutically equivalent products.

- BC** Controlled-release tablets, controlled-release capsules, and controlled-release injectables (controlled-release products for which such bioequivalence data are available have been coded AB).
- BD** Active ingredients and dosage forms with documented bioequivalence problems.
- BE** Enteric-coated oral dosage forms (enteric-coated oral dosage forms for which bioequivalence data are available are coded AB).
- BP** Active ingredients and dosage forms with POTENTIAL bioequivalence problems.
- BR** Suppositories or enemas for systemic use.
- BS** Products having standard deficiencies (if the drug standards for an active ingredient in a particular dosage form are found by FDA to be deficient so as to prevent an FDA evaluation of either pharmaceutical or therapeutic equivalence, all drug products containing that active ingredient in that dosage form are coded BS. For example, if the standards permit a wide variation in pharmacologically active components of the active ingredient such that pharmaceutical equivalence is in question, all products containing that active ingredient in that dosage form are coded BS).
- BT** Topical products.
- BX** Insufficient data—These products are presumed to be therapeutically inequivalent until adequate information becomes available for full evaluation of therapeutic equivalence.