

FDA CODES AND THERAPEUTIC DEFINITIONS

"A" CODES

Drug products that are considered 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.
- AN** Solutions and powders for aerosolization.
- AO** Injectable oil solutions.
- AP** Injectable aqueous solutions, and in certain instances, intravenous non-aqueous solutions.
- AT** Topical products.

"B" CODES

Drug products that the FDA does not at this time consider to be therapeutically equivalent to other pharmaceutically equivalent products.

- B*** Drug products that require further FDA investigation and review to determine therapeutic equivalence.
- BC** Extended-release dosage forms such as capsules, injectables, and tablets (extended-release products for which such bioequivalence data are available have been coded AB).
- BD** Active ingredients and dosage forms with documented bioequivalence problems.
- BE** Delayed-release oral dosage forms (delayed-release oral dosage forms for which bioequivalence data are available are coded AB).
- BN** Products in aerosol-nebulizer drug delivery systems.
- BP** Active ingredients and dosage forms with POTENTIAL bioequivalence problems.
- BR** Suppositories or enemas for systemic absorption.
- 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).
- BT** Topical products with bioequivalence issues.
- BX** Insufficient data—These products are presumed to be therapeutically inequivalent until adequate information becomes available for full evaluation of therapeutic equivalence.

REFERENCE

U.S. Food and Drug Administration. Approved Drug Products with Therapeutic Equivalence Evaluations. Orange Book Preface. 42nd Edition. <https://www.fda.gov/media/71474/download>. Accessed December 21, 2022.