INFORMATION ON PRESCRIPTION DRUG SUBSTITUTIONS

The FDA classifies as therapeutically equivalent products that are approved as safe and effective; are pharmaceutical equivalents (i.e., contain identical amounts of the same active drug ingredient in the same dosage form and route of administration and meet compendial or other applicable standards of strength, quality, purity, and identity); are bioequivalent (i.e., do not present a known or potential bioequivalence problem and meet an acceptable in vitro, or in some cases in vivo, or both, standard--or, if they do present such a known or potential problem, are shown to meet an appropriate bioequivalence standard);are adequately labeled; and are manufactured in compliance with current Good Manufacturing Practice (GMP) regulations. Products that meet these criteria are considered therapeutically equivalent even though they may differ in certain other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colorings, flavorings, and preservatives), expiration date/time, minor aspects of labeling (e.g., presence of specific pharmacokinetic information), and storage conditions. The FDA takes the position that when differences of these types are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed ("dispense as written") as a medical necessity ("brand medically necessary"). With this limitation, however, the FDA believes that products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.

SwyftScripts may substitute a generic drug for a prescribed drug unless the prescriber writes, “Dispense as written.” If questions arise as to therapeutic equivalent SwyftScripts will contact the drug manufacturer and/or consult the FDA Orange Book.