An FDA-approved generic drug is a drug shown to be equivalent to a brand-name drug in terms of active ingredient, dosage, strength, safety, quality, the way it works and the time for it to work. Companies making generic drugs must pass them through the same quality standards for manufacturing, testing and packaging as brand-name companies. All generic drug facilities must meet FDA standards of “good manufacturing practices” (GMP). FDA conducts more than 3,500 inspections per year to ensure standards are met.

Most generic drugs achieve near equivalence to brand name drugs (Two large FDA studies found a difference of only 3.5% in area under the curve (AUC) and 4.3% in the maximum peak serum concentration (Cmax) comparing generic vs. brand-name drugs).

Generics are 89% of dispensed prescriptions but only 27% of total spending on medicine.

An authorized generic is distributed by a generic company but manufactured by the original brand-name company.

Learn more about generic drugs by visiting chestfoundation.org/generics

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