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.

FDA requirements for bioequivalence is between 80-125% of the reference drug which means the generic drug could have 20% less activity (or 25% more activity) than the brand-name drug.

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.

Generic drugs amount to a savings of more than $4 billion every week for patients.

Drugs (generic and non-generic) with a “Narrow Therapeutic Index” (NTI) may require close monitoring and clinical observation. NTIs have a narrowly defined range between the risk of side effects and the therapeutic benefit.

Narrow Therapeutic Drugs (NTI) drugs include antiarrhythmic, antiepileptic and transplant drugs, levothyroxine, warfarin, and antirejection medications. FDA suggests clinical observation when a patient is on an NTI medication.

GENERIC DRUGS

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.

REMEmBER

Generic drugs are the same as brand-name drugs in:

- Safety and quality
- Dosage
- Mechanism of action
- The way they should be taken
- The way you use them

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

These patient education materials, including the infographic, and other collateral pieces are generously supported by Mylan.

Read the CHEST Foundation Patient Education Disclosure at https://foundation.chestnet.org/patient-education-disclosure/