

Information About Generic Drugs

Health professionals and consumers can be assured that the FDA-approved generic drugs on the MAC list meet the same rigid standards as the brand-name drugs. To gain FDA approval, a generic drug must:

- Contain the same active ingredients as the brand-name drug
- Be identical in strength, dosage form and route of administration
- Have the same use indications
- Be bioequivalent
- Meet the same batch requirements for identity, strength, purity and quality
- Be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for brand-name products

Based on the FDA's determination of therapeutic equivalence between generic and brand-name drug products, the FDA concludes that:

- Additional clinical tests or examinations by health care providers are not needed when a generic drug is substituted for the brand name drug
- It is not necessary for health care providers to approach any one therapeutic class of drug products, including drugs regarded as narrow therapeutic range drugs, differently from any other class