Pharmaceutical Equivalence

Lab test results and other documentation from the generic manufacturer are reviewed by FDA to demonstrate that:

- The generic drug has the same active ingredient(s) as the brand-name drug.
- The generic drug has the same dosage form as the brand-name drug.
- The generic drug has the same strength and route of administration as the brand-name drug.
- The generic drug has the same indications as the brand-name drug.
- The inactive ingredients of the generic drug are safe and don’t change how the drug works.
- The generic drug will work as intended for a reasonable amount of time before expiring.

Bioequivalence

Comparisons—often in human volunteers who take both the generic and brand-name drugs—ensure that:

- The generic drug performs the same in the human body as the brand-name drug.
- The generic drug is as safe and effective as the brand-name drug.

Appropriate Container and Labeling

FDA inspection of the container and labeling demonstrates that:

- The generic drug’s label is the same as the brand-name drug’s label, with some exceptions—such as indications protected by patents or exclusivity.
- The generic drug is sold and shipped in an appropriate container.

Appropriate Manufacturing

FDA inspection of facilities demonstrates that:

- The generic drug meets the same requirements for identity, strength, purity, and quality as the brand-name drug does.
- The manufacturer is capable of making the generic drug correctly and consistently.

Visit www.FDA.gov/GenericDrugs to learn more.