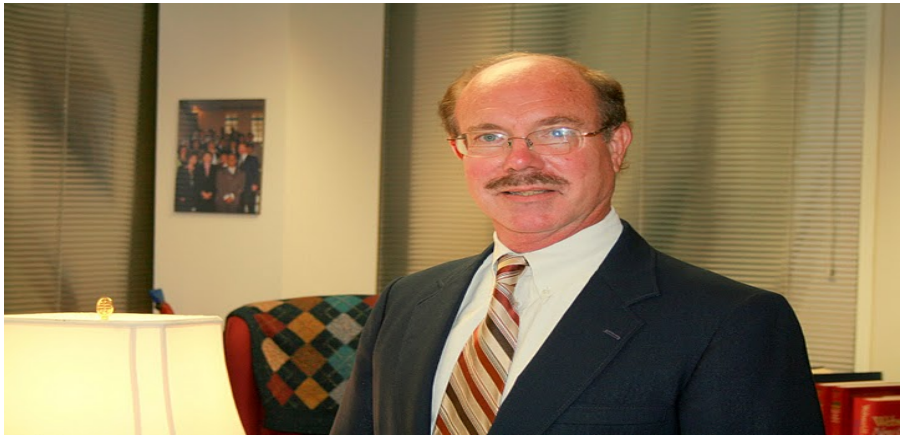
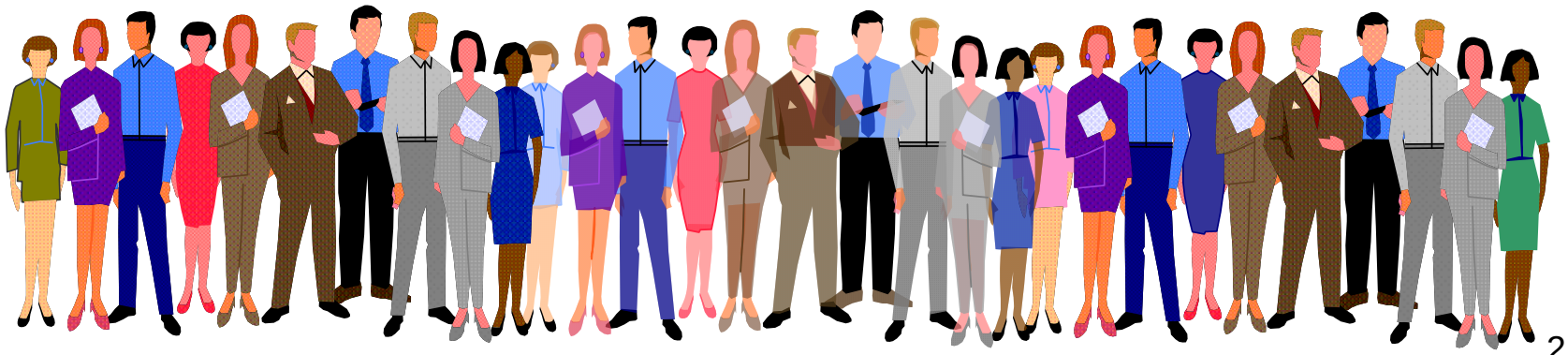
Generic Drugs



Robert L. West
Deputy Director
Office of Generic Drugs

OGD Mission:

To ensure through a scientific and regulatory process, that generic drugs are safe and effective for the American public.



Did you know that generic drugs...

- Are safe and effective alternatives to brand name drugs
- Reduce the cost of prescription drugs for both consumers and the government
- Represent 70% of the total prescriptions dispensed in the US
- Saved American consumers $824 billion in the last decade
- Save approximately $53 for every prescription sold

Also…

- Each year, more than 2.6 billion prescriptions are filled in the U.S. using generic drugs.
- Compare that amount to approximately 1.2 billion brand-name prescriptions dispensed each year.

In order to receive FDA approval, generic drugs must:

- contain the same active ingredient
- be the same strength
- be the same dosage form (tablet, capsule, etc.), and
- have the same route of administration (oral, topical, injectable, etc.) as the brand name drug.

Other Requirements

- In addition to being pharmaceutically equivalent, generic drugs must also be "bioequivalent" to the brand name drug.
- That means the generic drug will work in the body in the same way (same amount goes into the body within the same time frame) and be as safe and effective as the brand name drug.
- These studies are the same studies brand manufacturers conduct when they make changes in their product after approval.

Generic Drugs are Equivalent

- Recent study to evaluate bioequivalence of generic drugs approved within a 12 year period when compared to the brand products.
- 2070 bioequivalence studies
- Mean standard deviation 1.00± 0.06 for Cmax (peak level) and 1.00 ± 0.04 for AUC (amount absorbed)

(Annals of Pharmacotherapy October, 2009)

In another analysis of hundreds of bioequivalence studies:

The measured differences between brand and generic drugs are the same as the differences between different lots of the SAME branded drugs.

Misinformation

There is a frequent misinterpretation of the bioequivalence of generic drugs.

The assertion that levels of the active ingredient in generic drugs may vary from minus 20% to plus 25% compared to the brand.

THIS IS NOT TRUE!

Statistics Involved

- Those numbers relate to the complex statistical calculation used to analyze bioequivalence studies.
- They do not represent the actual difference in the amount of active ingredient a patient's bloodstream.
- Actual differences are the numbers found in the recent studies.

Brand Name Drug vs. Generic Drug Review Process

Brand Name Requirements	Generic Requirements
1. Chemistry	1. Chemistry
2. Manufacturing	2. Manufacturing
3. Testing	3. Testing
4. Labeling	4. Labeling
5. Inspections	5. Inspections
6. Animal Studies	
7. Clinical Studies	6. Bioequivalence
8. Bioavailability	

Only Differences

- Development of the active ingredient
- Pre-clinical animal studies for safety and efficacy
- Human clinical trials to prove the efficacy and safety of the active ingredient

Result

Generic drugs are less expensive because it isn't necessary to repeat:

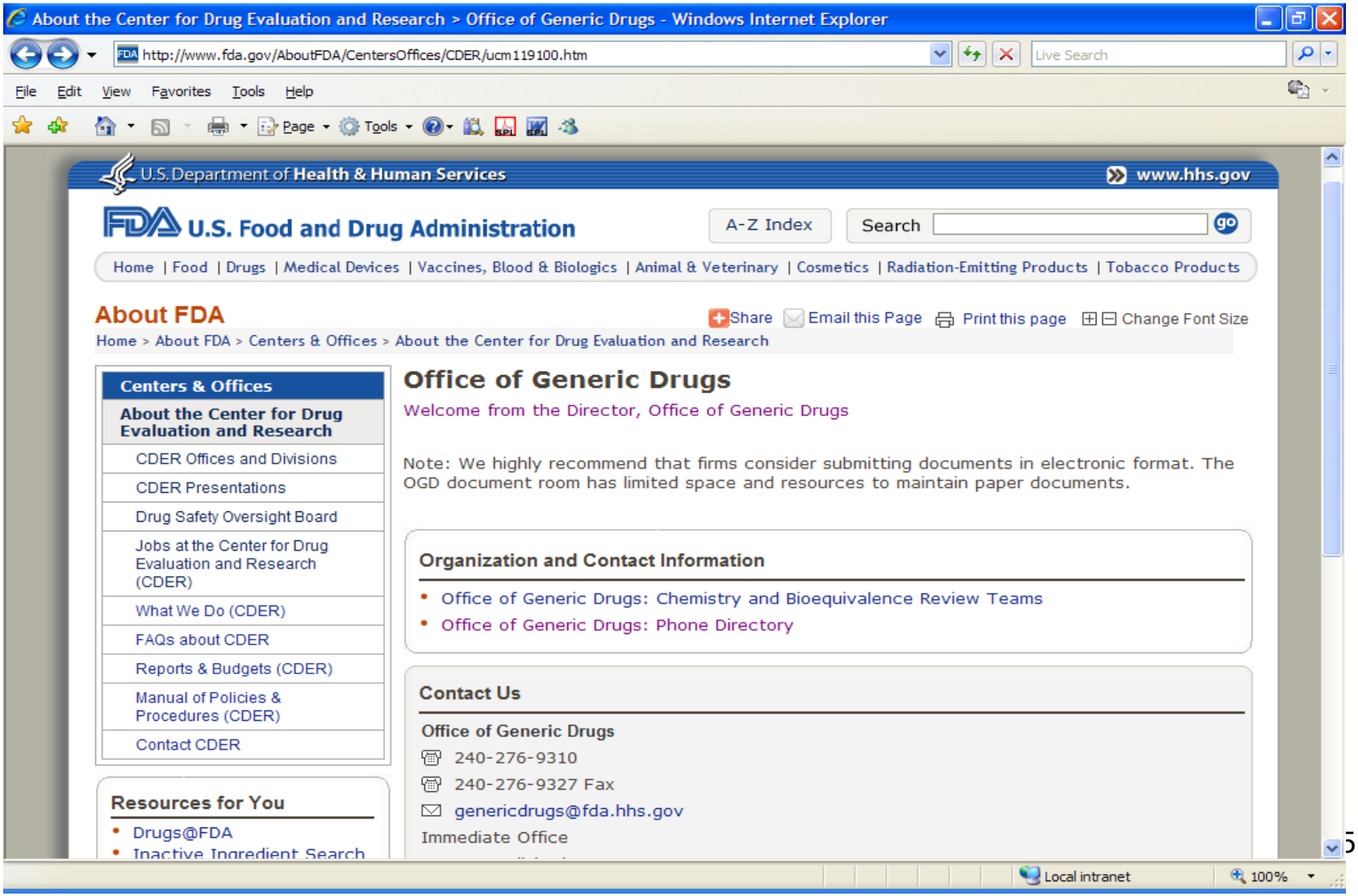
- Discovery
- Pre-clinical studies
- Clinical studies (repeating would be unethical)

Generic firms generally don't do advertising and promotion.

When will FDA approve a generic for the medication I am taking?

- FDA generally approves a generic drug on the first day it legally can do so.
- Consumers have timely access to high quality generic drug products.

OGD Website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Organization and Contact Information
Office of Generic Drugs: Chemistry and Bioequivalence Review Teams
Office of Generic Drugs: Phone Directory
Contact Us
Office of Generic Drugs
240-276-9310
240-276-9327 Fax
genericdrugs@fda.hhs.gov
Immediate Office
Local intranet
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Questions???

- Contact OGD:
  - E-mail: genericdrugs@fda.hhs.gov