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Generic Drugs: **Myths and Facts**

Important Information

- Do not attempt to speed up the video.
- The Post Test will only unlock after the entire video has been viewed.
- The video can be paused and resumed later.

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Program Objectives

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This program will show you how generic drugs are developed and approved in the US. After you finish the program, you will be able to:

- Describe the standards the FDA uses to approve generic drugs
- Discuss bioequivalence
- List several strategies used by pharmaceutical companies to undermine generic competition
- Identify two advantages of using generic drugs

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1 INTRODUCTION

A Generic Drug is…

A drug for which the original patent has expired, so the drug can now be produced by manufacturers other than the original patent-holding company.

What's the difference between a generic drug and a generic name?

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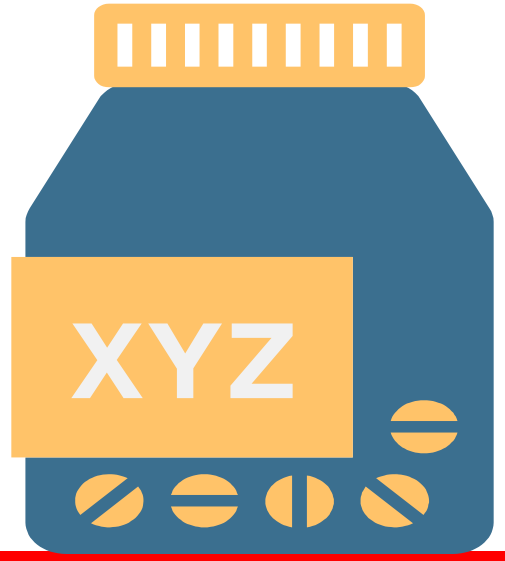
- Every drug has a generic name.
- Individual drug companies may or may not assign trade names to their versions of the drug, but the generic name remains the same regardless of the manufacturer.
- The drug company that first manufactures a drug usually (but not always) uses a brand name to sell that drug.

Generic Drug Names

- Since 1961, U.S. generic names have been assigned by the United States Adopted Names (USAN) Council.
- Many other countries use generic names assigned by the World Health Organization's International Non-Proprietary Names (INN) Program.
- For most drugs, the USAN Council and INN Program stems and generic names are the same.
- Some INN stems:
  - vir = antiviral
  - buvir = antiviral NS5B RNA polymerase inhibitors
  - lutamide = nonsteroidal anti-androgen
  - gab = gabamimetic agent
  - tide = peptides and glycopeptides



Patent Life of a Drug

- In the U.S., patent life lasts for 20 years from the date the patent application is filed.
- Patent applications are usually made early in drug testing.
- Drug testing and applying for drug approval takes years, so by the time a drug is on the market, it usually has 7-10 years of patent life left.

The "Hatch-Waxman Act"

(Drug Price Competition and Patent Term Restoration Act of 1984)

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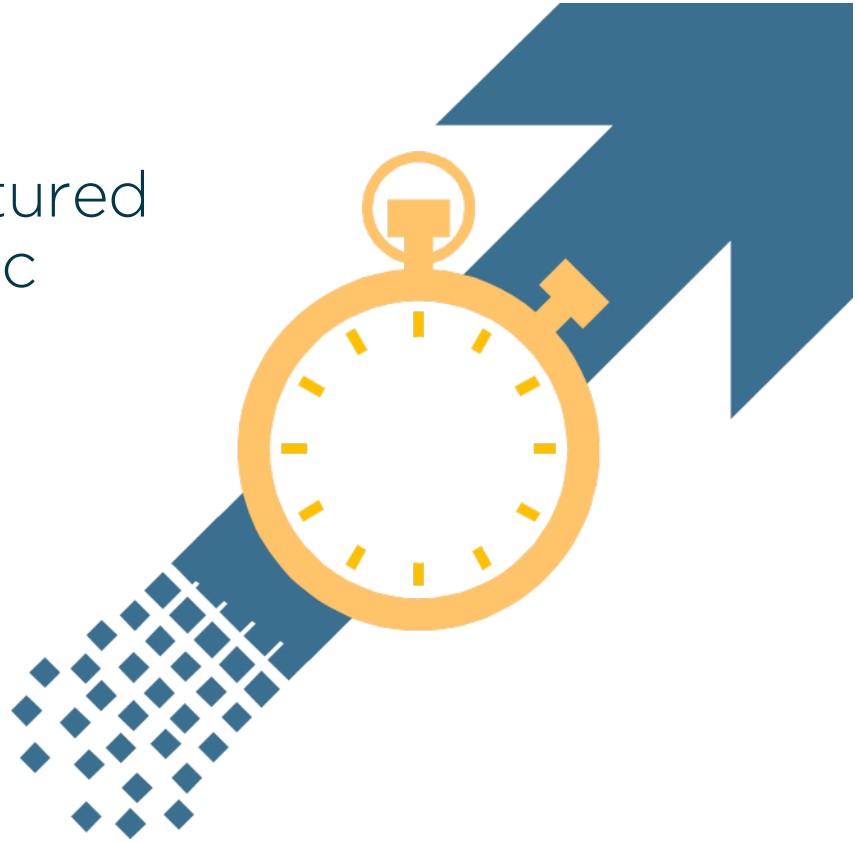
For new molecular entities, the Hatch-Waxman Act allows the patent term to be extended for up to 14 years after a drug has been approved and is on the market.

Hatch-Waxman Act

- Hatch-Waxman also provides additional periods during which the FDA may not approve a generic application.
- Under Hatch-Waxman, **new combinations, new dosage forms, and new uses** receive three additional years of exclusivity during which the FDA cannot approve a generic.
- **New combinations, new dosage forms** and **new uses** also may be covered by new patents with expiration dates extending well beyond the expiration dates of the original patents.
- Hatch-Waxman allowed the expansion of the generic drug industry and increased competition in the brand name industry.

Patent Expiration

- When a patent (and additional periods of exclusivity) expire, a drug may be manufactured and sold under its generic name as a generic drug by other companies.



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2 EXTENDING PATENT LIFE

Evergreening: **Extending Patent Life**

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- Pharmaceutical manufacturers may apply for patent extensions for minor changes in method of delivery or type of capsule or tablet.
- Generic drug manufacturers can be blocked from marketing a drug for up to 2.5 years until a patent dispute is settled.

Patent Extension: **Reformulations**

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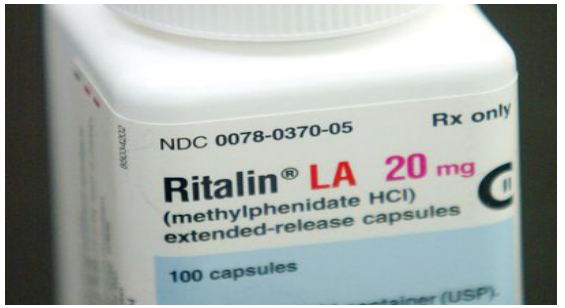
Delayed-release preparations include:

- Controlled-release (CR)
- Sustained-release (SR)
- Extended-release (XL)
- Long-acting (LA)



New Patents: **Minor Changes in Dosing**

Yasmin ⇄ **Yaz**

ethinyl estradiol **30 mcg** / Drospirenone **3 mg**

ethinyl estradiol **20 mcg** / Drospirenone **3 mg**

AndroGel ⇄ **AndroGel**

Testosterone **1%** / Testosterone **1.62%**

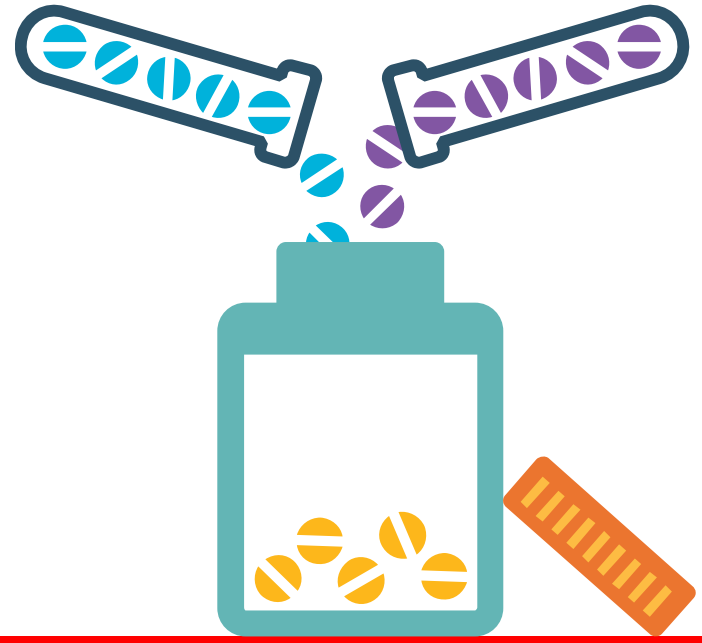
New Patents: **Fixed-Dose Combinations**

Fixed-dose combinations are two or more drugs in one pill.

Fixed-dose combinations are eligible for a new patent even if both drugs are available as generic drugs.

These drugs:

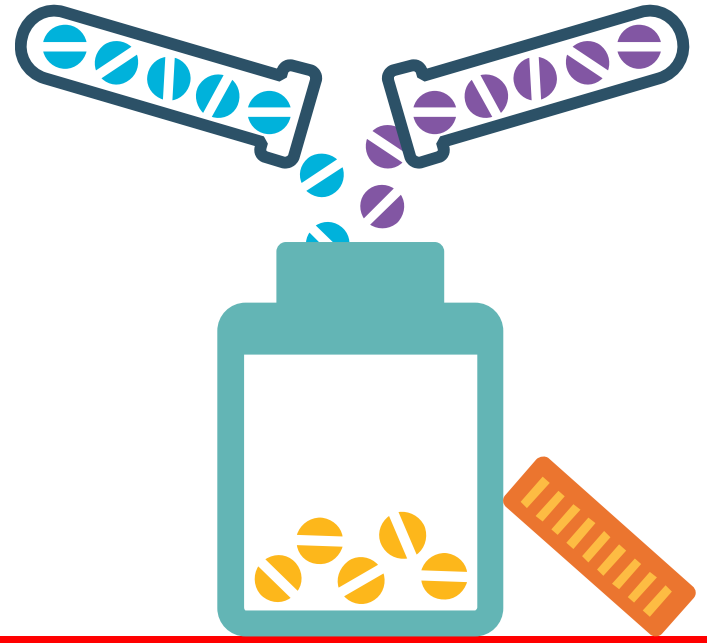
- Are often more expensive than their components.
- Provide less flexibility in dosing options.



New Patents: **Fixed-Dose Combinations**

Some combination products *(for example, some HIV products)* **enhance compliance.**

However, in many cases, writing a prescription for the individual drugs preserves dosing flexibility and often saves patients money.



Example: **Alendronate**

- **Fosamax plus D (alendronate and cholecalciferol)** is patent-protected and costs about six times as much as generic alendronate.
- Alendronate and other bisphosphonates must be taken with calcium *(all trials tested the combination).*
- Calcium supplements are often formulated with **vitamin D**, but calcium cannot be formulated with bisphosphonates.
- Because patients still need to take additional calcium with Fosamax plus D, the total tablet burden remains the same.

New Patents are Granted
for **Combinations of Generic Drugs**

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Can you name the two generically available drugs in the following branded products?

Advair

Diclegis

Symbicort

Diovan HCT

Branded Combinations of Generic Drugs Include:

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Advair	Diclegis	Diovan HCT	Symbicort
fluticasone + salmeterol	*doxylamine succinate + pyridoxine hydrochloride (vitamin B-6)*	*valsartan + hydrochlorothiazide*	*budesonide + formoterol*

New Patents are Granted
for **Combinations of Branded and Generic Drugs**

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Can you name the patented and generic drugs in the following branded products?

Combinations of a Branded and Generic Drug Include:

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Janumet	Vytorin	Benicar HCT
sitagliptin + *metformin*	*ezetimibe* + *simvastatin*	*olmesartan medoxomil* + *hydrochlorothiazide*

New Patents are Granted for Enantiomers

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- Many drugs are a racemic mixture, containing equal parts of the left-handed and right-handed enantiomer.
- Receptors may only accept one enantiomer. Effectively one-half of the drug molecules in a racemic drug are active and the other half are inactive.

Left-handed
enantiomers of drugs use

the prefix

"es" *or* **"levo"**

Right-handed
enantiomers of drugs use

the prefix

"ar" *or* **"dextro"**

Enantiomers

- Enantiomers are chiral molecules that are mirror images of one another.
- It has become common practice to introduce a drug as a racemic mixture.
- Then, when the patent is close to expiring, the company releases the active enantiomer as a “new, improved” product.

Ask yourself:
Why is the racemic mixture marketed first when it was technically possible to market the active enantiomer initially?

Enantiomers

Ask yourself:

Can you name a drug released first as a racemic mixture and then as a single isomer?

Nexium (esomeprazole), **A Best-Selling Drug,** is an **Enantiomer**

Omeprazole

Esomeprazole

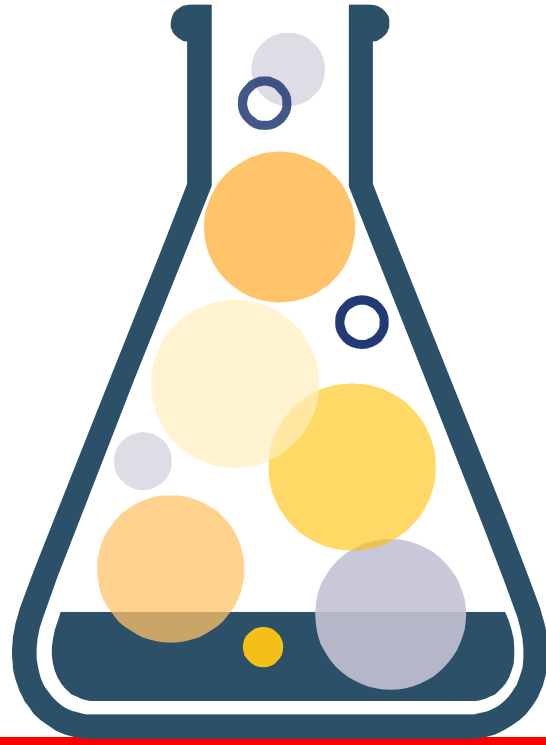
Other Examples Include:

- Escitalopram (Lexapro) is the ***S*-enantiomer** of citalopram (Celexa).
- Armodafanil (NuVigil) is the ***R*-enantiomer** of modafanil (ProVigil).
- Adderall is a 3:1 mixture of ***d*- and *l*-enantiomers** containing a fixed ratio (1:1:1:1) of amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, and dextroamphetamine sulfate.
- Levalbuterol (Xopenex) is the ***l*-enantiomer** of albuterol (Proventil, Ventolin, etc.)

Are Enantiomers Better?

There is no strong scientific support for the superiority of these isolated enantiomers.

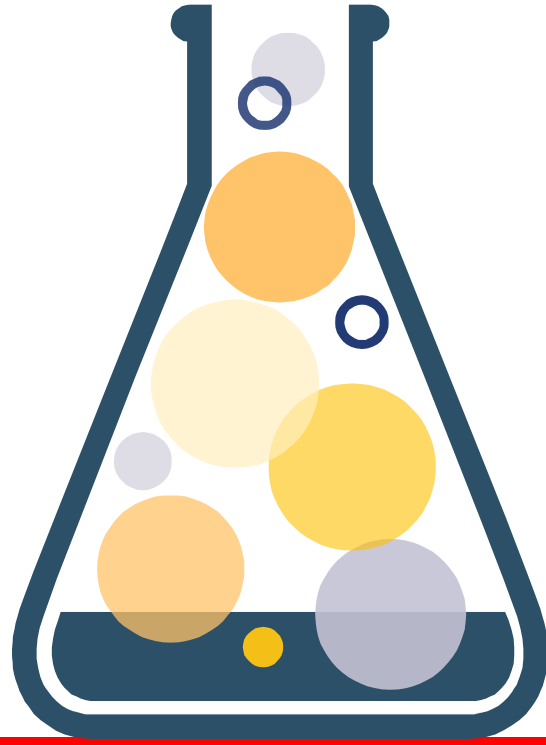
No trials have demonstrated a therapeutic advantage of esomeprazole over omeprazole when used at equivalent therapeutic doses.



Citalopram and Escitalopram

For escitalopram (Lexapro), the *S*-enantiomer is responsible for almost all serotonin reuptake inhibition.

However, there is no compelling evidence to support claims that escitalopram is more effective or has a faster onset of action than citalopram (Celexa), and side effects are similar.



Adderall

Adderall combines the *d*-isomer dextroamphetamine (Dexedrine) with the *l*-isomer, which is less potent.

The half-life of *d*-amphetamine is 10-11 hours.

A full day's effectiveness can be ensured by delivering an adequate morning dose of generic dextroamphetamine.

There is no need for the Adderall XR formulation, which delivers half of the dose initially, and the remainder 4 hours post-ingestion.

Other "**Next Generation**" Products

Another tactic used when a drug is going off-patent is to release a metabolite or prodrug of the originator drug.

Ask yourself:
Can you name a drug that is a metabolite or a prodrug of a branded drug?

Examples of Metabolites

- Desvenlafaxine (Pristiq) and venlafaxine (Effexor)
- Desloratidine (Clarinex) and loratidine (Claritin)
- Acyclovir (Zovirax) and valacyclovir (Valtrex)

An example of a prodrug:

Lisdexamfetamine (Vyvanse)

Example of a Prodrug: Vyvanse

Lisdexamfetamine (Vyvanse), dextroamphetamine linked to a lysine molecule, is almost immediately cleaved to its components upon ingestion.

Peak levels of dextroamphetamine may be reached earlier than other formulations, but there is no advantage to this.

Earlier peak levels could theoretically increase rates of adverse effects.

Are Metabolites and Prodrugs better?

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Although there are exceptions, many metabolites, analogs, and prodrugs have no advantage over the originator drug.

For example:

No studies have compared loratadine (Claritin) with its main metabolite, desloratidine (Clarinex), and there is no evidence that desloratidine is superior.

New Patents: **New Indications**

- A new FDA-approved use (“indication”) can extend the patent life of a drug.
- Some drugs are renamed upon approval for a new indication.
- Renaming confuses prescribers into prescribing the brand for which there is no generic equivalent.

New Trademarks: **Renamed Drugs**

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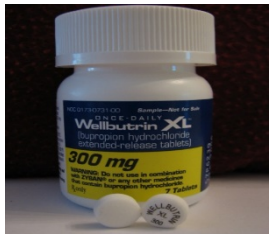
Fluoxetine = PROZAC fluoxetine hydrochloride = Sarafem fluoxetine hydrochloride

Bupropion = 

= 

Sildenafil = 

= 

Drugs May Also Be Renamed for Veterinary Purposes: **Reconcile**

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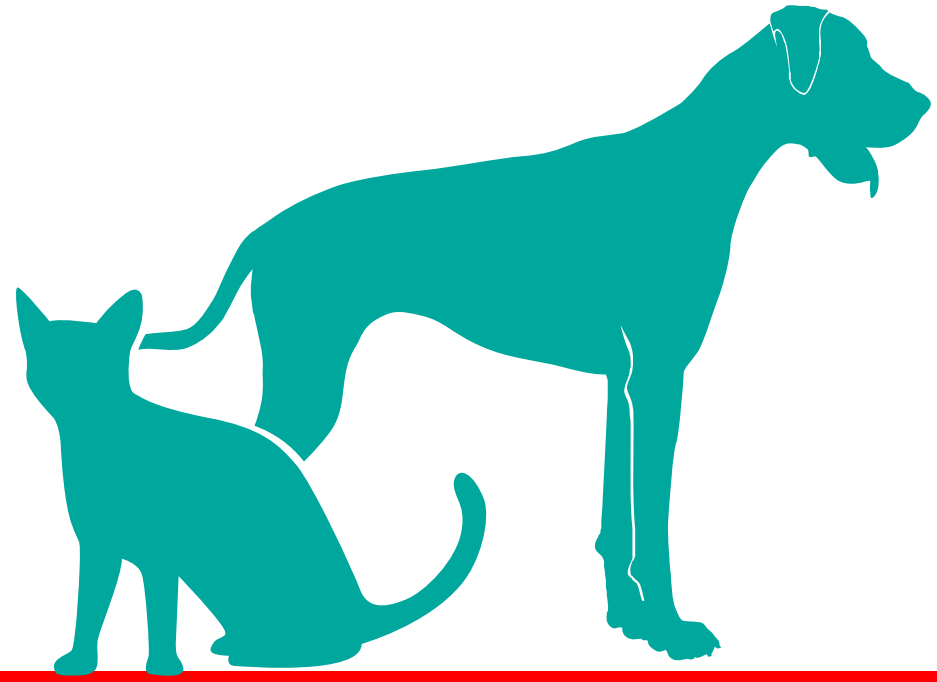
Elanco, Lilly's animal health division, markets Reconcile® (fluoxetine HCl) "for the treatment of canine separation anxiety in conjunction with a behavior modification plan."

Reconcile is formulated in 8, 16, 32 and 64 mg chewable tablets.



Why you should avoid prescribing renamed drugs

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- A renamed drug may be exactly the same medicine, but its name may be trademarked.
- Even if there is a generic available for the **original** drug, in some states a pharmacist cannot substitute a generic medication for the **renamed** drug.
- It is always best to use the generic name of a drug on any prescription - whether branded or generic.

To Preserve Market Share, Companies May Also:

- Manufacture their own generics
- Refine promotional strategies
- Foster brand loyalty
- Reformulate off-patent products
- Try to switch a drug from prescription to nonprescription (over-the-counter) status

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3 BRANDED *vs.* GENERIC DRUGS

Prescribers are Most Familiar with Branded Drugs

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We all think that we are not affected by advertising, but most of us can correctly associate images, logos, and taglines with the products advertised.

Ask yourself:
Can you identify the drug associated with the following images?

Prescribers are Most Familiar with Branded Drugs

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Prescribers are Most Familiar with Branded Drugs

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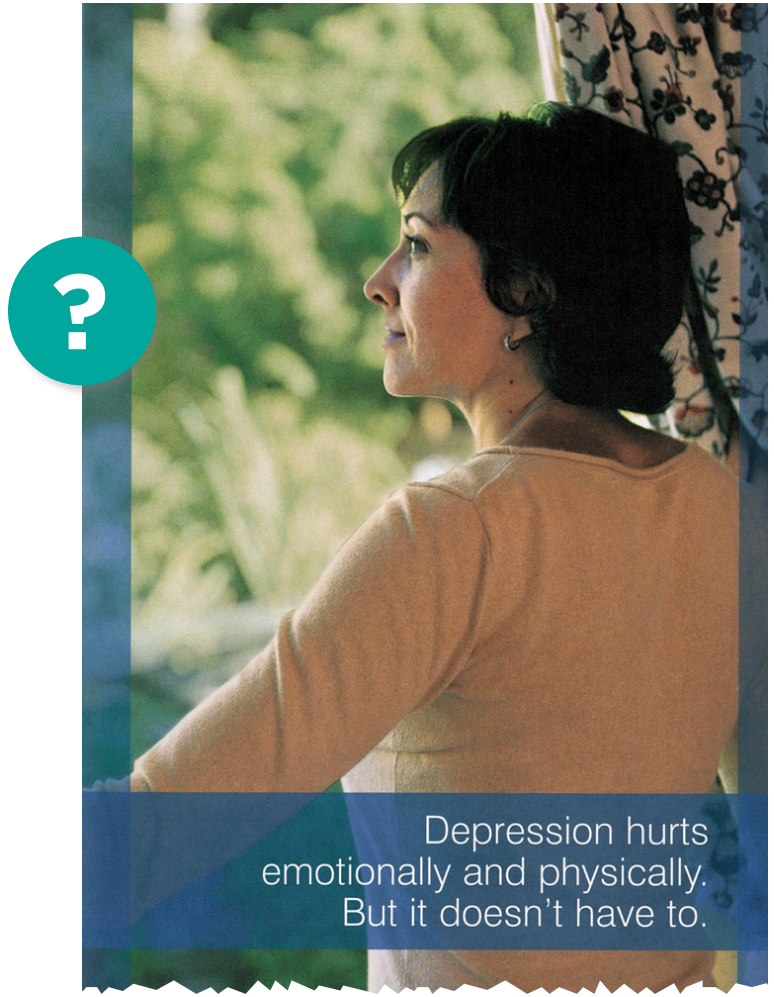
Prescribers are Most Familiar with Branded Drugs

Prescribers are Most Familiar with Branded Drugs



Prescribers are Most Familiar with Branded Drugs

Did you correctly identify more than you thought you would?

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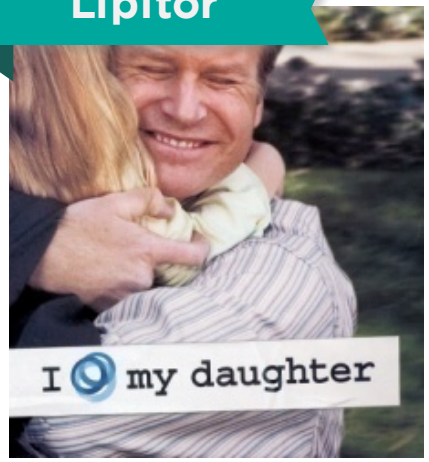
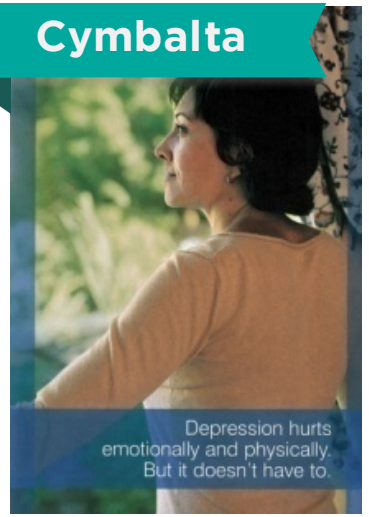
Lipitor



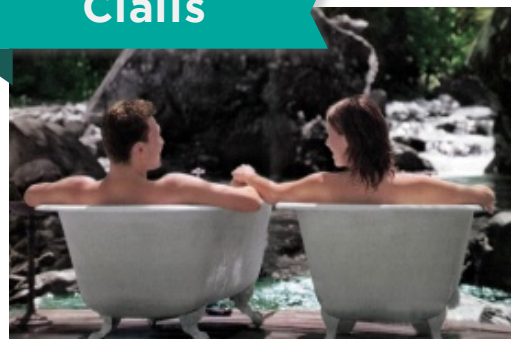
Advair

Cymbalta



Lunesta

Cialis



Nexium

Effective Advertising

The fact that we can name the products means that the ads have served their purpose.

Ads in consumer and medical literature are meant to keep specific drug names uppermost in our minds when we reach for our pens and prescription pads.

Prescribers Are More Familiar With Brand Names Than Generic Names

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Ask yourself:
What are the generic names of the following drugs?

- Lipitor
- Nexium
- Advair
- Plavix
- Seroquel
- Remicade
- Abilify
- Sovaldi
- Diovan

How many could you identify?

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Lipitor	Atorvastatin	Remicade	Infliximab
Nexium	Esomeprazole	Abilify	Aripiprazole
Advair	Fluticasone and salmeterol	Sovaldi	Sofosbuvir
Plavix	Clopidogrel	Diovan	Valsartan
Seroquel	Quetiapine		

Consider This:

- If you can remember only the brand, not the generic name, of drugs, then you are being affected by promotion.
- It's not a coincidence that brand names are easier to remember.
- Much money is spent on creating memorable brand names. Some firms specialize in naming drugs.

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4 MYTHS and FACTS ABOUT GENERIC DRUGS

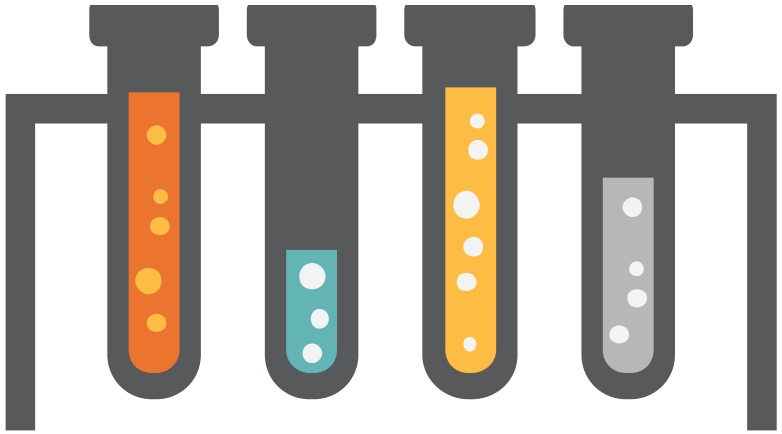
www.doh.dc.gov

Did you know that…

- Generic drugs are NOT inferior in quality to branded drugs.
- Generic pills do NOT contain less active drug than branded pills.
- Inactive ingredients in generics do NOT affect absorption.
- Patients who are well-controlled on a branded medication CAN be switched to a generic medication.
- Bioequivalence studies in healthy people DO inform us about drug levels in sick people.

NDAs and ANDAs

- New chemical entities are approved under the **New Drug Application** (NDA) process.
- Generic drugs are approved under the **Abbreviated New Drug Application** (ANDA) process.

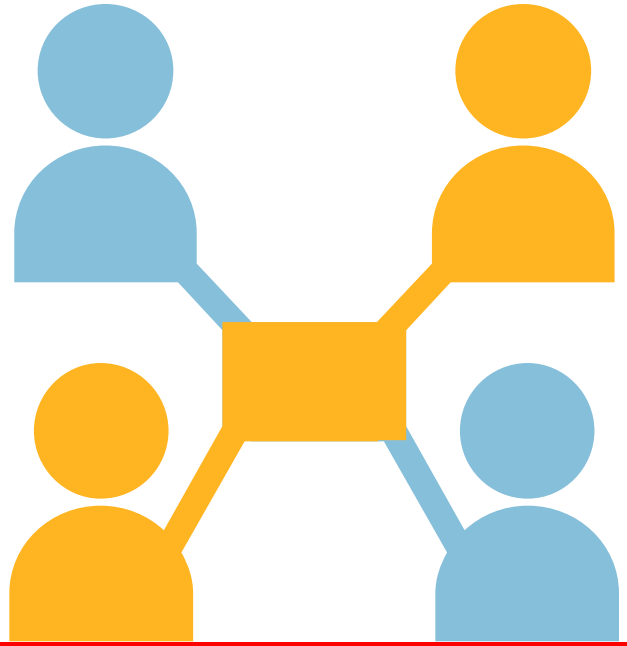


ANDA Review

- **Pre-clinical and clinical testing does not have to be repeated for generics.**
- **ANDA reviews include:**
  - Bioequivalence evaluation
  - Chemistry/microbiologic evaluation
  - Inspection of the manufacturing facility
  - Review of the proposed label

Bioequivalence: Definition

Bioequivalence is: "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." (FDA)



"I've heard that generic drugs are weaker than branded drugs."

- Not true!
- The FDA uses the same standard for variability between **brand and generic** drugs as it uses for variability between **different batches** of branded drugs.

FDA Requirements for Generic Drugs

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A generic drug must:

- Contain the same active ingredients as the innovator new drug
  - Inactive ingredients may vary
- 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 innovator products

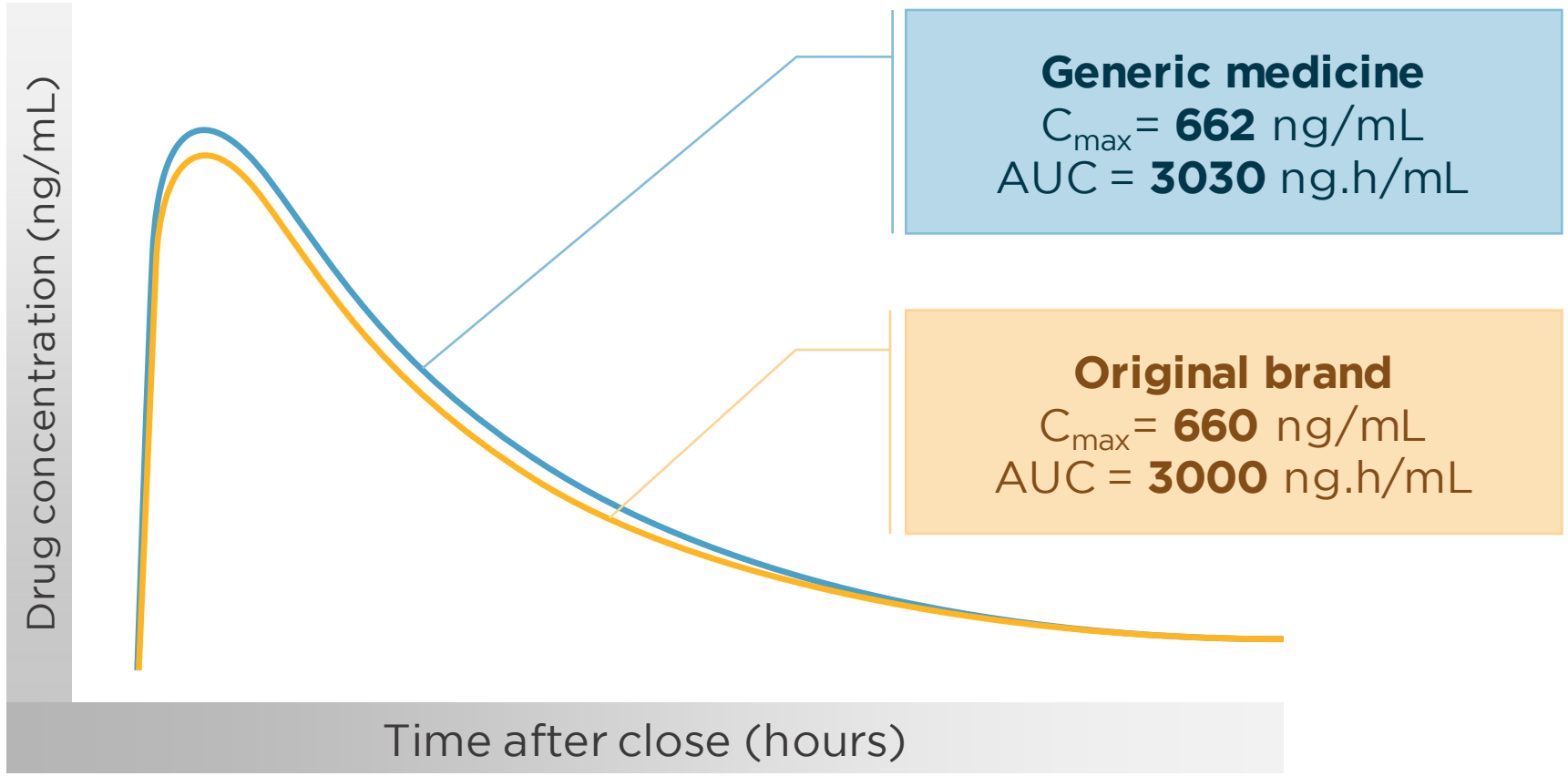
"Really? But I've heard that generic drugs can contain 20% less active drug than branded drugs."

- Very misleading! Here are the facts:

Generic Drug Facts:

- In order for the FDA to approve a generic drug, the 90% confidence intervals (CIs) for generic drug levels must be between 80%-125% for AUC (area under the time-concentration curve) and Cmax (peak plasma concentration) of the reference (branded) drug.
- This does **not** mean **that concentrations** of the reference (branded) and test (generic) drug differ by 20%.
- **If drug concentrations differ by about 10%, the CIs will fall outside of range.**

Mean Concentration-Time Curves for Single Oral Doses of Two Brands



(NPS News 2006) (44)
http://www.nps.org.au

Bioequivalence Testing: **Drug A**

- Let's say the AUC for generic Drug A, compared to reference Drug A, results in the following serum concentrations in six people:*

  110%, 120%, 110%, 110%, 90%, 110%

  Mean (average) = 110%, **90% CI**= 99% -115%

- The average concentration of generic Drug A is 110% of the concentration of reference Drug A. The CIs tell us that there is 90% certainty that the true range lies between 99% and 115%.
- The test drug is considered bioequivalent to the reference drug.
- This drug passes the bioequivalence test

** Normally, bioequivalence studies test at least 24 subjects*

Bioequivalence Testing: **Drug B**

- The AUC for generic Drug B compared to reference Drug B, results in the following serum concentrations in six people:

  110%, 170%, 50%, 130%, 90%, 110%

  Mean (average) = 110%, **90% CI**= 75%-140%

- The average concentration of generic Drug B is 110% of the concentration of reference Drug B. The CIs tell us that there is 90% certainty that the true range lies between 75% and 140%.

(Meyer 1998)

- The confidence intervals are too wide, so the range of possible values is too broad. This difference in concentration could affect clinical results.
- The test drug is NOT considered bioequivalent to the reference drug.
- This drug fails the bioequivalence test
- The test drug fails to establish bioequivalence with the reference drug.

Generic Drugs are Equivalent to Branded Drugs

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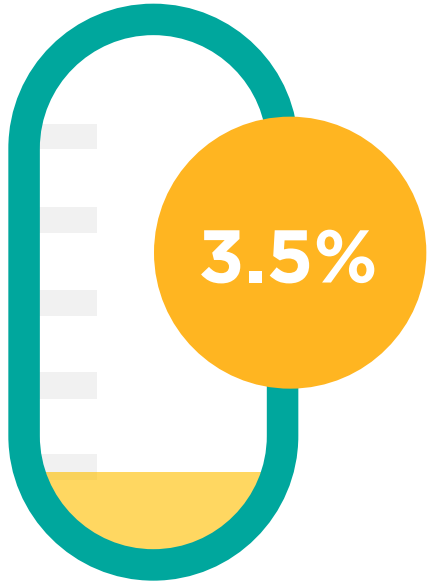
A study that examined 2,070 single-dose clinical bioequivalence studies of oral generic medicines approved by the FDA showed that the average difference in absorption into the body between the generic and the originator was 3.5% - comparable to differences between two different batches of the original drug.



(Davit 2009)

Clinical Equivalence of Generic and Brand-name Drugs

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Clinical equivalence is even more important than bioequivalence. A systematic review and meta-analysis of clinical equivalence of generic and brand-name drugs used in cardiovascular disease found that **generic and branded drugs were clinically equivalent in:**

- All 5 RCTs of warfarin
- All 7 RCTs of β-blockers
- Ten of 11 RCTs of diuretics
- Five of 7 RCTs of calcium channel blockers
- All 3 RCTs of antiplatelet agents
- Two RCTs of statins
- One RCT of angiotensin-converting enzyme inhibitors
- One RCT of α-blockers

(Kesselheim 2008)

"I've heard that studies in healthy people don't represent my sick patients."

- Bioequivalence studies in healthy people are performed by both generic and branded drug manufacturers.
- Pharmaceutical companies use bioequivalence studies to test marketed forms of a drug that are different than the form used in clinical trials, or modifications to marketed dosage forms.

No evidence to date has shown that two dosage forms that are bioequivalent in normal subjects are not bioequivalent in sick people.

"I've heard that inactive ingredients in generics may affect drug levels."

A generic drug may have different excipients (fillers, binders, coatings, flavoring, coloring) than competing branded (or generic) drugs, but:

- The range of excipients used in pharmaceutical manufacture is small.
- The same excipients are used by many companies.
- A patient may be allergic or intolerant to a specific excipient in a generic – or a branded - drug.

Bioequivalence studies test the final product to be marketed.

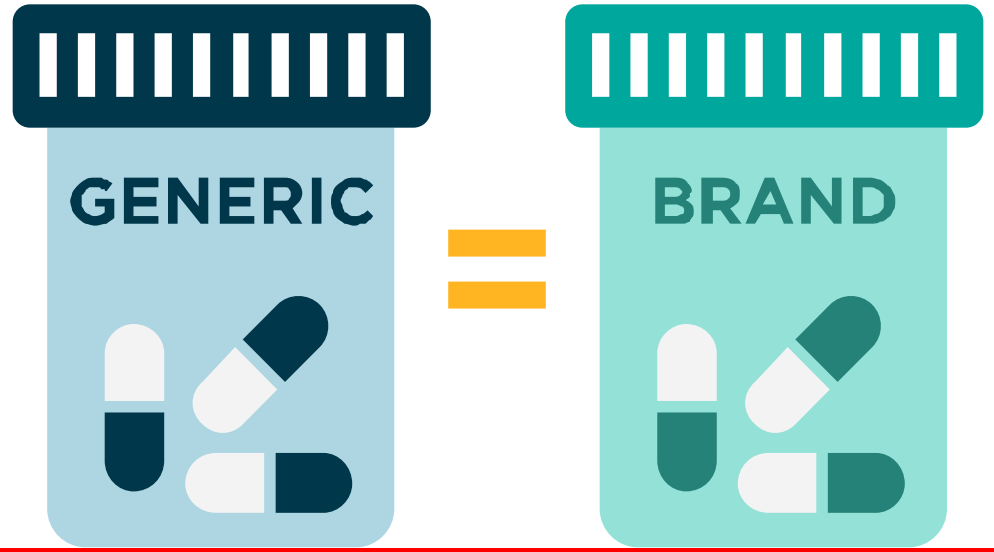
If excipients affected drug concentrations, the drug would FAIL the test for bioequivalence

Narrow Therapeutic Index Drugs

- Narrow therapeutic index drugs are those for which the range between therapeutic and toxic doses is small.
  - Examples include aminoglycosides, digoxin, and phenytoin.
- Critical dose drugs are narrow therapeutic index drugs (i.e. warfarin) that:
  - Require monitoring
  - Have a steep dose-response curve
  - Underdosing or overdosing of critical dose drugs may have serious adverse effects

Narrow Therapeutic Index Drugs

- Narrow therapeutic index drugs must be titrated carefully.
- Different patients may require very different doses.
- However, the dose required by an individual usually does not vary greatly.



"I've heard that generics should be avoided for some drugs"

- Studies show that there is **no need to avoid generic substitution** in narrow therapeutic index drugs.
- Clinical equivalence was reported in all 5 RCTs (100%) of warfarin.
- Clinical equivalence was reported in one RCT of class 1 antiarrhythmic agents. (Kesselheim 2008)

"I've heard that generics should be avoided for antiepileptics."

There is **no need to avoid generic substitution for antiepileptics.** A systematic review and meta-analysis of clinical equivalence of anti-seizure drugs found that generic substitution made no difference in seizures.

(Kesselheim 2010)

Drug Problem?

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- If product failure of any branded or generic drug is suspected, notify the FDA.
- If possible, include lot number and expiration date, patient drug therapy profile, and the basis for suspecting failure.
- If possible, keep samples of the drug for testing.

1-800-FDA-1088

www.fda.gov/Safety/MedWatch

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5 ADVANTAGES OF GENERIC DRUGS

www.doh.dc.gov

Generic Drugs

- Are equivalent to branded drugs
- Are made by reliable manufacturers
  - Brand-name firms manufacture about 50% of generics.
- Save patients money
- Increase adherence
- Are time-tested

Costs of Generic Drugs

- About three-quarters of FDA-approved drugs have generic equivalents.
- Average cost of an Rx for a branded drug is $111.02.
- Average cost of an Rx for a generic drug is $32.23.

(Good and Valentino 2007)

Generic Drugs Save Money

- In the U.S., $250 billion is spent on prescription drugs annually.
- Switching to generics could save 11% in overall drug costs.
- Three-quarters of insured Americans (86% of seniors in Medicare Part D) have tiered pharmacy benefits, so pay more for branded drugs.

(Kohl 2007)

Generic Drugs Improve Adherence

- In a 2005 survey, 25% of insured patients and 51% of uninsured patients said that they or a family member had not filled a prescription, had cut pills, or had skipped medical treatment because of cost.

  (Prescription Drug Trends 2007)

- Generic drugs improve adherence because patients can afford them. In 3-tiered plans, patients who received generics filled 12.6% more prescriptions in the next year than those who received non-preferred branded drugs.

  (Shrank 2006)

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The FDA's Position

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"The American public can be confident that when a generic drug product is approved, it has met the rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency. Through review of data on proposed products, the Office of Generic Drugs assures that generic products will perform the same as their respective brand name reference products."

Gary J. Buehler - Former Director, FDA Office of Generic Drugs FDA

GDUFA

The Generic Drug User Fee Amendments of 2012 (GDUFA) is a law that requires a fee from drug manufacturers to review applications for generic drugs and inspect facilities.

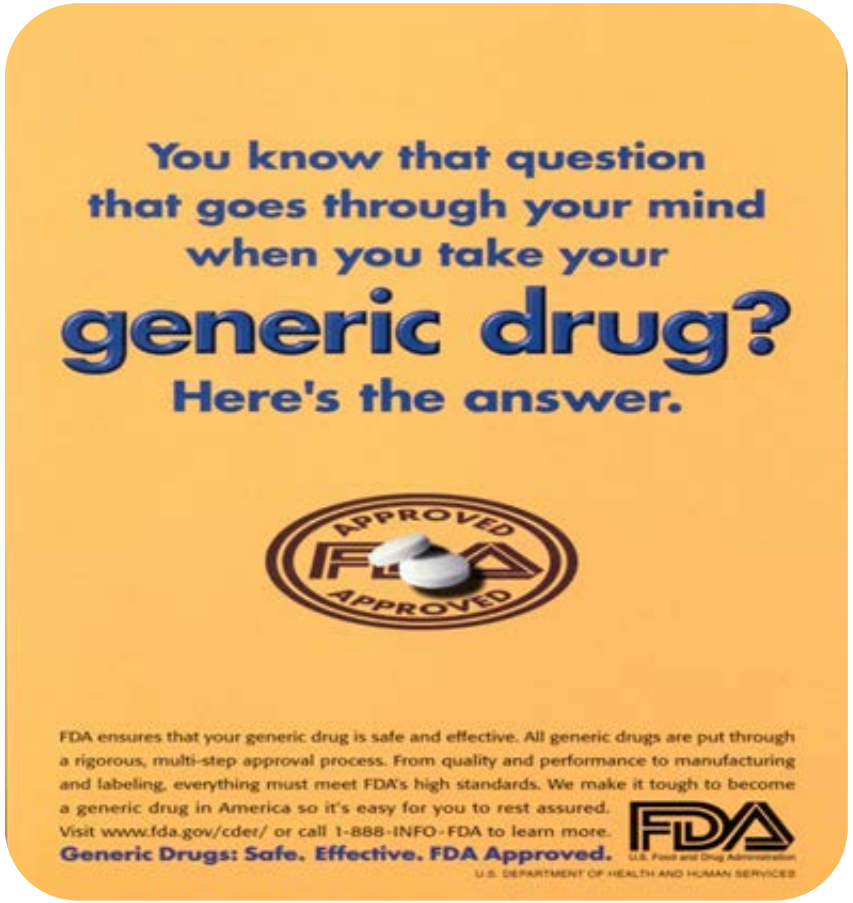
GDUFA will bring more timeliness to the review of low-cost, high-quality generic drugs and will ensure that foreign and domestic manufacturing facilities are held to a high standard.

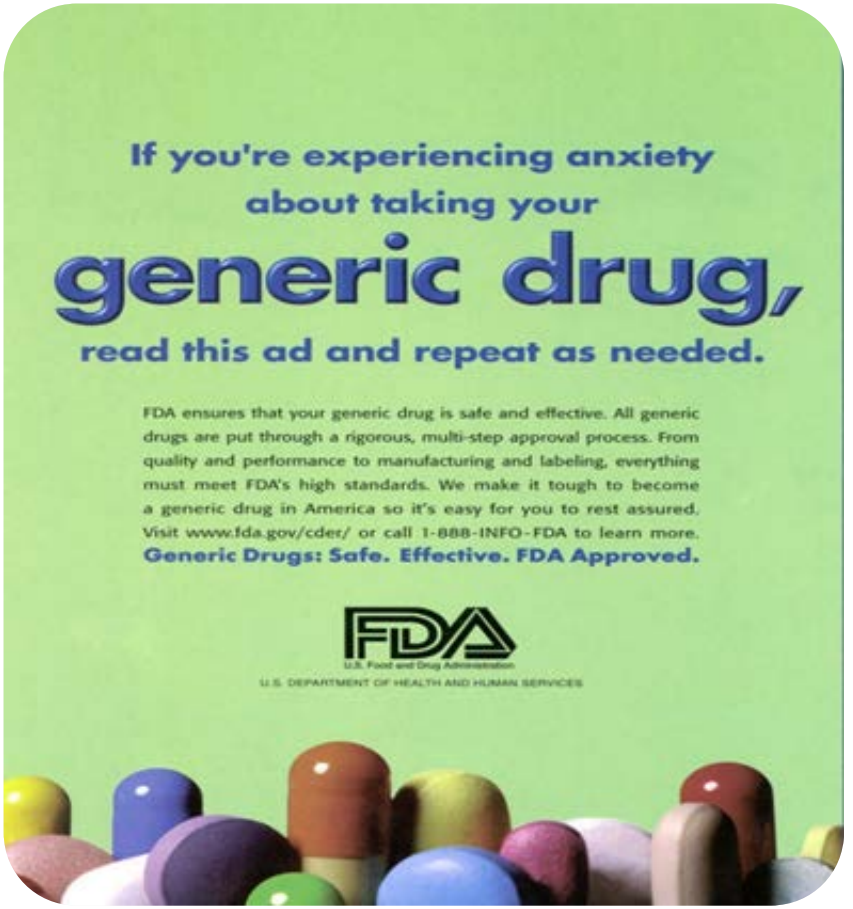
PDUFA

Since 1992, prescription drug manufacturers have paid a fee to the FDA as part of the Prescription Drug User Fee Act (PDUFA).

PDUFA has enabled the FDA to expedite its drug approval process for new, branded prescription drugs.

FDA Public Service Ads



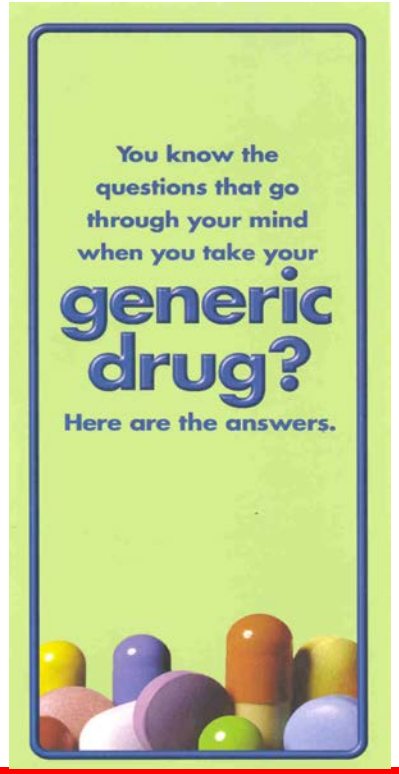


FDA Public Service Ads

dpapubs@fda.hhs.gov

301-827-1243

1-800-FDA-1088



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MORE RESOURCES

Please visit DCRx for more information on these and other treatment-related subjects.

doh.dc.gov/dcrx