What You Want to Know About Generic Drugs

Generic Drugs: Safe. Effective.

FDA-Approved.

What do you want to know about ALL the medicines you use....
brand-name and generic?

- **safe and effective**
- **affordable and available**
- **use with confidence**

Myths about Generic Drugs

- Generics…are not as safe
- Generics…are not as potent
- Generics…take longer to act in the body
- Generics…are made in sub-standard facilities

What You Want to Know About Generic Drugs

I. **How FDA assures that generics:**
   - **are Safe. Effective. FDA-approved.**
   - **are an affordable alternative**
   - **can be used with confidence**

What You Want to Know About Generic Drugs

II. How FDA and the administration are working to make more generic medicines available to the American public

What You Want to Know About Generic Drugs

Brand-name drug	Generic drug
• supplied by one drug company • sold under drug company's trademarked name	• may be supplied by more than one company • may be sold under active ingredient(s) name(s)

What is a generic drug?

A copy of a brand-name drug, which must have the:

- **same quality**
- **same safety**
- **same strength**

What You Want to Know About Generic Drugs

Both brand name and generics drugs:

- **are approved by the FDA**
- **must meet the same FDA standards for quality**

Generic Competition

It is essential to have brand-name and generic drugs available.

Generic Competition

- helps keep drug costs down
- encourages research
- helps keep insurance premiums down
- saves consumers $8 to $10 billion yearly

Patent Protection

A patent:

- protects the investment of the drug company that developed the drug (the manufacturer)
- gives the drug company the sole right to sell the drug while the patent is in effect

Patent Protection

When the patents on a brand-name drug near expiration, drug companies that want to manufacture a generic can apply to the FDA to sell a generic version of the drug.

Generic Drug Review

- Much the same as new, brand name drug review
- 8 major parts

Generic Drug Review

1. **FDA-approved generic drugs must have**

- **same active ingredient(s)**
- **same labeled strength**
- **same dosage form**
- **same administration**

Generic Drug Review

2. **The drug company must show the generic drug is "bioequivalent" to the brand-name drug.**
   - **active ingredient works in the same way**
   - **active ingredient works in the same amount of time**

Generic Drug Review

3. **The generic drug's labeling must be basically the same as that of the approved brand-name drug.**

Generic Drug Review

4. **The drug company must:**
   - **fully document the generic drug's chemistry, manufacturing steps, and quality control measures**
   - **detail each step of the process**

Generic Drug Review

5. The raw materials and the finished product must meet USP specifications, if these have been set.

   USP-United States Pharmacopeia

Generic Drug Review

6. **The drug company must:**
   - **show that its generic drug maintains stability as labeled before it can be sold**
   - **continue to monitor drug's stability**

Generic Drug Review

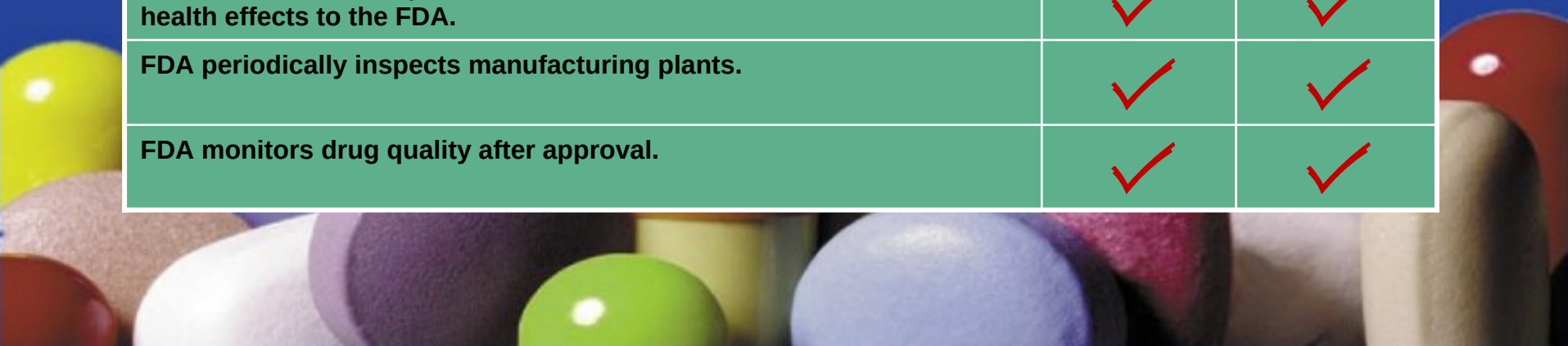
7. **The drug company must:**
   - comply with federal regulations for current good manufacturing practices
   - give a full description of the facilities it uses to manufacture, process, test, package, label, and control the drug

Generic Drug Review

8. **Inspection at the proposed manufacturing site ensures that the firm:**
   - **is capable of meeting commitments of the application**
   - **can manufacture the product consistently**

FDA Requirements for Brand-Name and Generic Drugs

	Brand Name Drug	Generic Drug
For reformulations of a brand-name drug or generic versions of a drug, FDA reviews data showing the drug is bioequivalent to the one used in the original safety and efficacy testing.	✓	✓
FDA evaluates the manufacturer's adherence to good manufacturing practices before the drug is marketed.	✓	✓
FDA reviews the active and inactive ingredients used in the formulation before the drug is marketed.	✓	✓
FDA reviews the actual drug product.	✓	✓
FDA reviews the drug's labeling.	✓	✓
Manufacturer must seek FDA approval before making major manufacturing changes or reformulating the drug.	✓	✓
Manufacturer must report adverse reactions and serious adverse health effects to the FDA.	✓	✓
FDA periodically inspects manufacturing plants.	✓	✓
FDA monitors drug quality after approval.	✓	✓



What You Want to Know About Generic Drugs

II. What the FDA and the administration are doing to make more generic medicines available to the American public

Making More Generics Available

A. Hatch-Waxman Act, or the Patent Term Restoration Act of 1984

B. President's 2003 budget increased FDA's funding to speed up generic drug reviews (more reviewers, etc.)

Making More Generics Available

C. "Improving Access to Generic Drugs" initiative

- **new regulatory processes to reduce time and cost of generic drug approvals**

Making More Generics Available

C. "Improving Access to Generic Drugs" initiative (continued)

- enhanced public and professional education

Making More Generics Available

C. "Improving Access to Generic Drugs" initiative (continued)

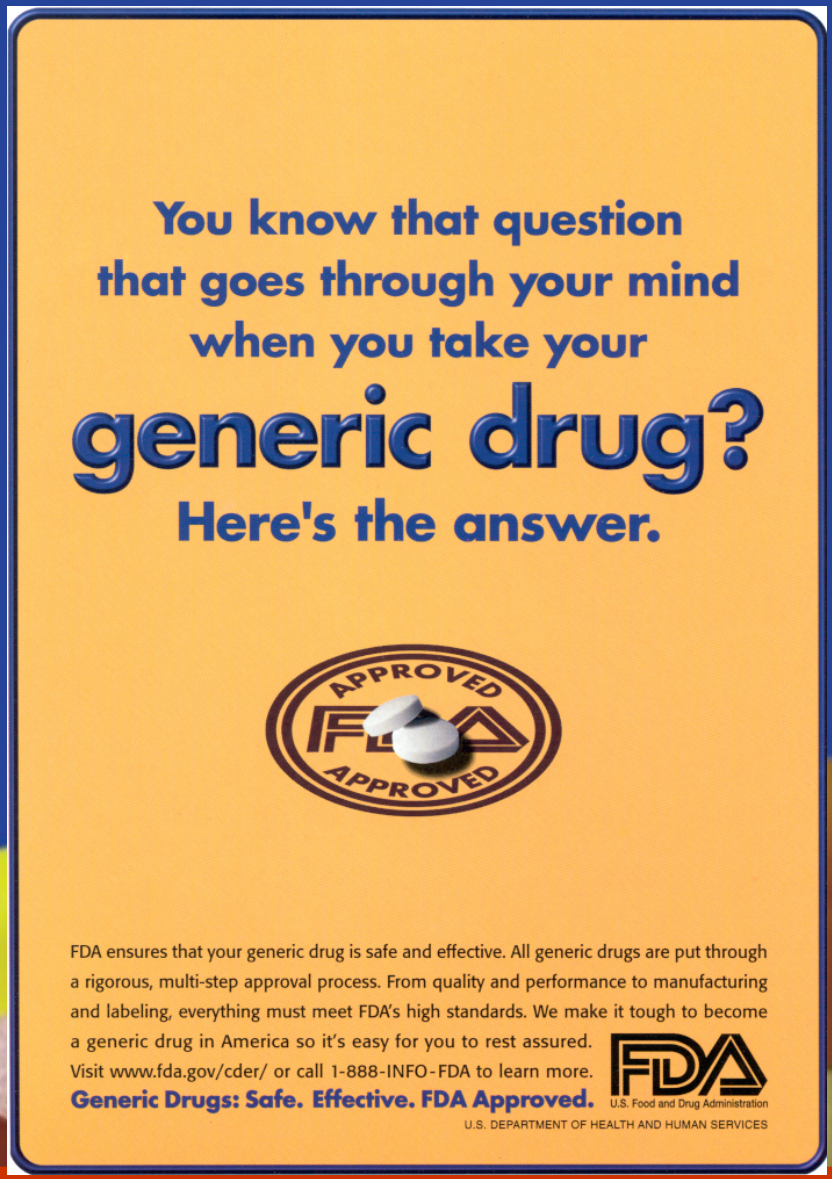
- enhanced scientific study of generic drugs

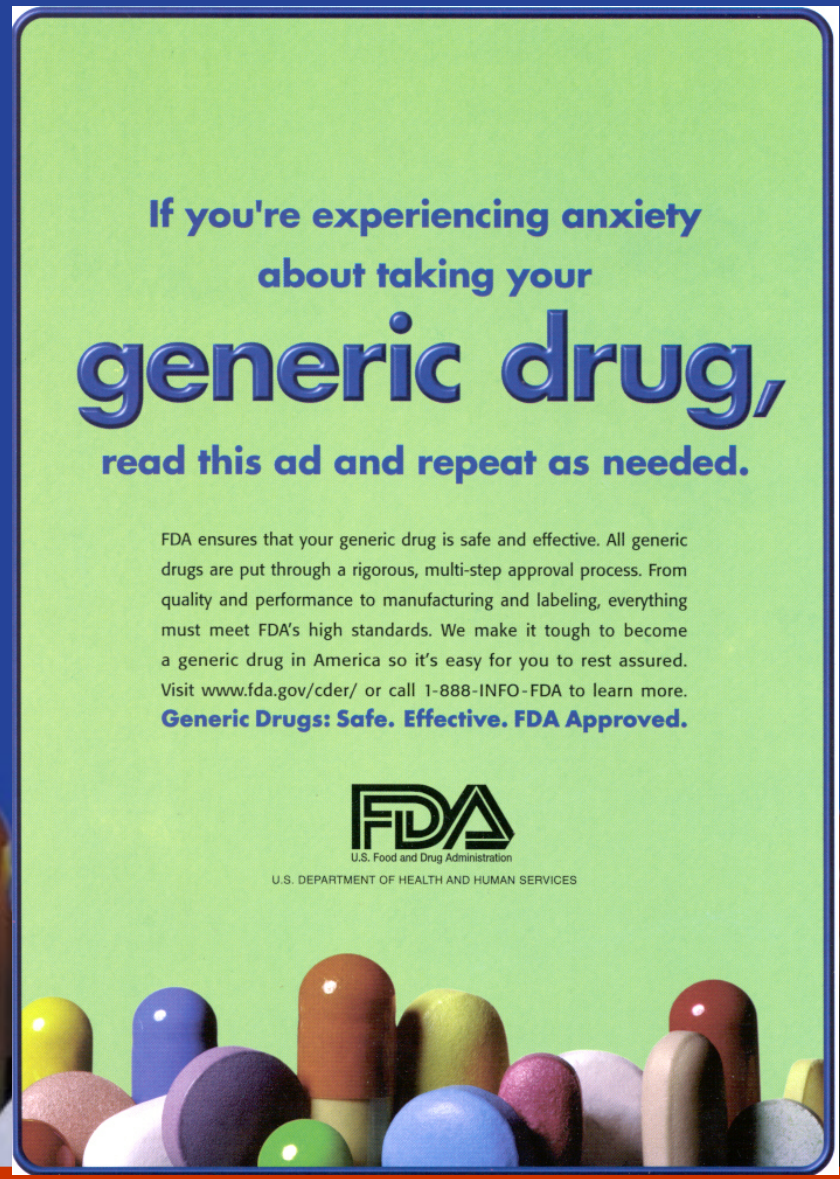
Making More Generics Available

C. "Improving Access to Generic Drugs" initiative (continued)

- **enhanced monitoring of the safety of generic drugs**

Print Public Service Ads for Consumers





Public Transportation Ads in U.S. Cities

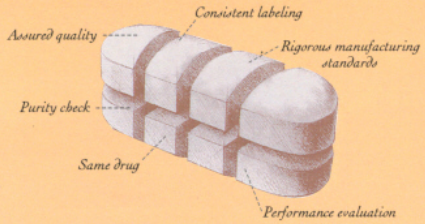
Consumer Brochure in English and Spanish

You know the questions that go through your mind when you take your

generic drug?

Here are the answers.

What is a generic drug?



When a brand-name drug's patent protection expires, generic versions of the drug can be created and sold. The generic version works like the brand-name drug in dosage, strength, performance and use, and must meet the same quality and safety standards. All generic drugs must be approved by FDA.

How does FDA ensure that my generic drug is as safe and effective as the brand-name drug?

All generic drugs are put through a rigorous, multi-step approval process that includes a review of scientific data on the generic drug's ingredients, performance and effectiveness. FDA also conducts continuous inspections of the manufacturing plant, and monitors drug quality—even after the generic drug has been approved.

If generic drugs and brand-name drugs have the same active ingredients, why do they look different?

The drugs look different because certain inactive ingredients—like colors and flavorings—may be different. These ingredients do not affect the performance of the generic drug in any way, but trademark laws in the U.S. do not allow a generic drug to look exactly like drugs already on the market.

Is my generic drug made by the same company that makes t brand-name drug?

Quite possibly, but not always. Brand-name fi are responsible for manufacturing approxima percent of generic drugs. They frequently ma versions of their own or other brand-name dr are also other approved companies that prod generic drugs.

Are generic drugs always made in the same kind of facilities as brand-name drugs?

Yes. Both brand-name and generic drug faci must meet the same standards of good ma practices. FDA will not permit drugs to be m substandard facilities. FDA conducts about 3 inspections a year to ensure standards are m

FDA makes it tough to become a generic dru America so you can feel confident about taki generic drugs. If you still want to learn more, t with your doctor, pharmacist, medical provide insurance company. Or call **1-888-INFO-FDA** **www.fda.gov/cder** today.

FDA
U.S. Food and Drug Administration

Generic Drugs: Safe. Effective. FDA Approved.

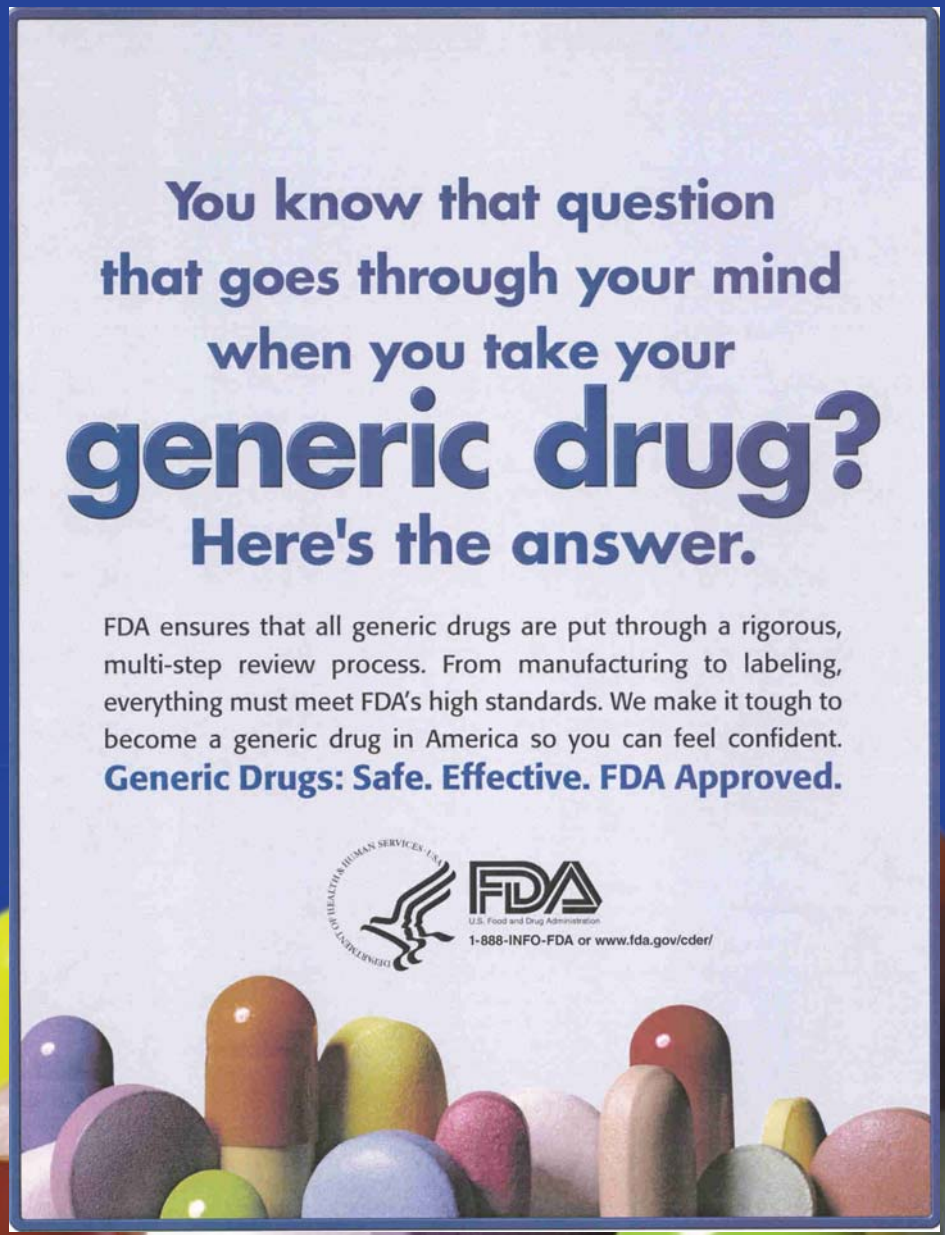
¿Qué son los

medicamentos genéricos

y por qué son importantes para usted?

Todo lo que necesita saber sobre los medicamentos genéricos.

Posters in English and Spanish



Blue Cross Blue Shield of Michigan Billboards

Posters Appearing in 4,000 Walgreens Pharmacies Nationwide

Making More Generics Available

D. FDA's generic drug Final Rule, 8-18-03

- **seeks to close legal loopholes in the Hatch Waxman Act that delay generic drug approval**

Making More Generics Available

D. FDA's generic drug Final Rule, 8-18-03 (continued)

- **implements an FTC recommendation to tighten the patent submission and listing process**

Making More Generics Available

D. FDA's generic drug Final Rule, 8-18-03 (continued)

- **clarifies the types of patents that must be submitted to the FDA**

Making More Generics Available

E. House and Senate passed a bill, "Greater Access to Affordable Pharmaceuticals Act"

- **complements FDA's final rule.**
- **FDA is working with Congress**

Myths and Facts about Generic Drugs

Myths and Facts about Generic Drugs

MYTH #1

Generics are not as safe as brand-name drugs.

Myths and Facts about Generic Drugs

FACT #1

Generics use the same ingredients, and

- **work the same in the body**
- **have the same risk-benefit profile**

Myths and Facts about Generic Drugs

MYTH #2

Generics are not as potent as brand-name drugs.

Myths and Facts about Generic Drugs

FACT #2

Generic drugs have the same quality, strength, purity and stability.

Myths and Facts about Generic Drugs

MYTH #3

Generics take longer to act in the body.

Myths and Facts about Generic Drugs

FACT #3

The generic drug delivers the same amount of active ingredient in the same time as the original drug.

Myths and Facts about Generic Drugs

MYTH #4

Brand-name drugs are made in modern manufacturing facilities, and generics are often made in sub-standard facilities.

Myths and Facts about Generic Drugs

FACT #4

Sub-standard facilities are not permitted by the FDA.

What you want to know about Generic Drugs

For more information on generic drugs, visit the FDA website at:

http://www.fda.gov/cder/ogd/index.htm

What you want to know about Generic Drugs

Contact your physician, pharmacist, or insurance company

for more information about your generic drugs.

Generic Drugs: Safe. Effective. FDA-Approved.

(Name of presenter)

(Title of presenter)

November 19, 2003

Sources

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   New FDA Initiative on *"Improving Access to Generic Drugs,"* June 12, 2003

   http://www.fda.gov/oc/initiatives/generics/whitepaper.html

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2. **FDA Fact Sheet**

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www.fda.gov/oc/initiatives/generics/fs_initiative.html

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3. FDA Fact Sheet

   FDA Acts to Lower Drug Prices By Implementing New Regulation to Improve

   Generic Drug Competition, June 12, 2003 -

   TODAY'S ACTION

   www.fda.gov/oc/initiatives/generics/fs_rule.html

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4. FDA Generic Drugs Final Rule and Initiative Information page

http://www.fda.gov/oc/initiatives/generics/default.htm

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5. Press Release

   FDA's New Regulation to Speed Access to Lower Cost Generic Drugs About to Take Effect August 8, 2003

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6. *FDA Consumer* article

   “Greater Access to Generic Drugs. New FDA initiatives to improve drug reviews and reduce legal loopholes.”
   FDA Consumer September-October 2003
   By Michelle Meadows

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7. Article

“ FDA Ensures Equivalence of Generic Drugs,” September 1999, article updated 2002

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9. Office of Generic Drugs Director's Update 7/8/03

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11. Generic Drugs: Safe. Effective.
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