



Office of Training and Communications (OTCOM)

Nancy Smith, PhD



CDER Forum for International Drug Regulatory Authorities



Mission

OTCOM supports the mission of
CDER/FDA through excellence in
innovative

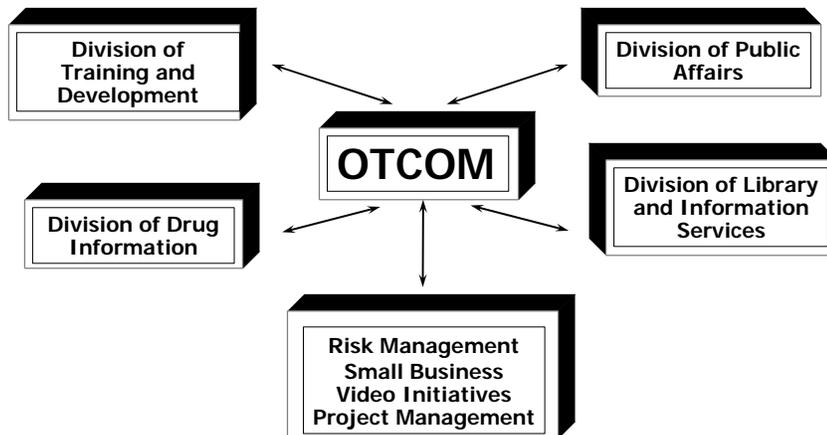
- Information exchange
- Employee performance
enhancement



CDER Forum for International Drug Regulatory Authorities



Organization



Drug Information Division Mission

Supporting OTCOM's mission of excellence in communications through information exchange by assisting all inquirers and providing useful, accurate information in a timely manner.





How Do We Communicate?

- **E-mails**
 - Druginfo@cder.fda.gov
 - ~2500 per month
- **Phone Calls**
 - (301)827-4573 or 888-INFO-FDA
 - ~ 3500 per month
- **Letters**
 - 5600 Fishers Lane, HFD-240
Rockville, MD 20857
 - ~ 600 per month



CDER Forum for International Drug Regulatory Authorities



Who Are Our Customers?

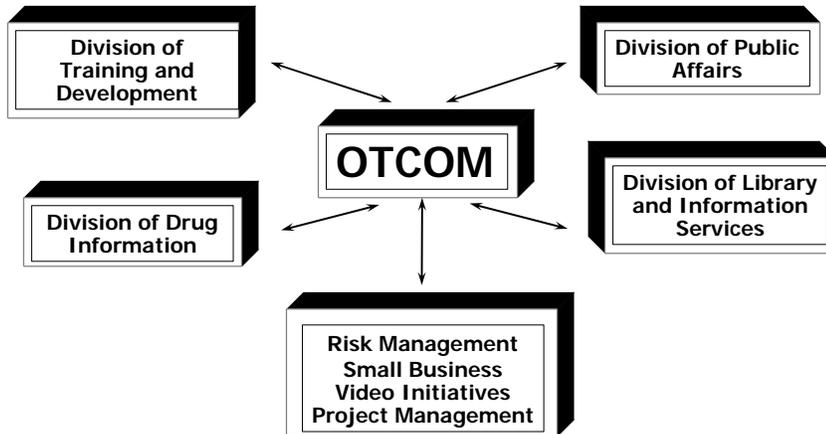
- **Industry**
- **Health Care Professionals**
- **Consumers**
- **FDA / Government**
- **Academia**
- **Law Enforcement**
- **Attorneys**
- **“Financial Interests”**



CDER Forum for International Drug Regulatory Authorities



Organization



CDER Forum for International Drug Regulatory Authorities



Providing Information to Consumers, Health Professionals and Industry on the Safe and Effective Use of Medical Products

Division of Public Affairs
CDER/Office of Training and Communications

Drug Educational Programs

Goal: Develop a multimedia educational program to build consumer and health-care professionals' confidence in the safety and effectiveness of drugs

Primary Audience: Consumers currently using drugs

Messages:

- * Drugs are approved by the FDA
- * Drugs are safe, effective and manufactured under FDA's quality standards



Drug Education Materials

- * Print Public Service Announcements
- * Brochure (English and Spanish)
- * Newspaper Article
- * Posters (English and Spanish)
- * FDA Consumer Magazine Article
- * Radio PSA (English and Spanish)
- * FDA Web Page
- * Pharmacist and Health Professional Web Course
- * Give-away items



You know what's in your medicine cabinet, but do you know what's in your medicines?



You might be surprised to know your over-the-counter medicine may contain the same active ingredient found in some prescription or controlled substance medications. Taking more than one medicine means you could be receiving too much of the same active ingredient. Learn more at www.fda.gov/oc/otc.

and more is not better. Know your medicines. Always read and compare labels. Ask consult your doctor or pharmacist if you have any questions. Take the time to be careful.

NCPD
National Council on Prescription Drug Information
FDA
U.S. Department of Health and Human Services

THE NEW
OVER-THE-COUNTER
MEDICINE LABEL...



...TAKE A LOOK!

oon, all over-the-counter medicines will have one thing in common.



Simplicity

The easy-to-read format of the new Drug Facts label will help consumers choose the over-the-counter medicine that's right for them. For more information, visit our web site at www.fda.gov/oc/otc or call 1-888-INFO-FDA.

U.S. Department of Health and Human Services

The New Label
—It's Clearly Better—

The New Over-the -Counter Medicine Label



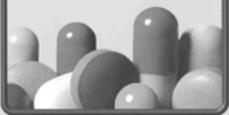
OTC Label Print Public Service Announcement Placements



Public Transportation Ads

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 the brand-name drug?

Quite possibly, but not always. Brand-name firms are responsible for manufacturing approximate percent of generic drugs. They frequently make versions of their own or other brand-name drug are also other approved companies that produce generic drugs.

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

Yes. Both brand-name and generic drug facilities must meet the same standards of good manufacturing practices. FDA will not permit drugs to be made in substandard facilities. FDA conducts about 3,500 inspections a year to ensure standards are met.



FDA makes it tough to become a generic drug in America so you can feel confident about taking generic drugs. If you still want to learn more, talk with your doctor, pharmacist, medical provider or insurance company. Or call 1-888-INFO-FDA or www.fda.gov/cder today.



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.



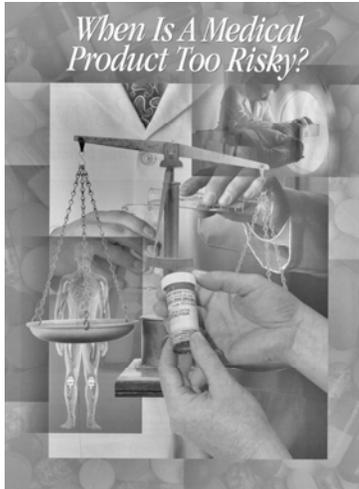
Appearing in 4,000 Walgreens Pharmacies



Generic bus ads



Blue Cross Blue Shield of Michigan Billboard



**Risk Management
Education Campaign**

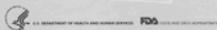


Think It Through...



ALL medicines, both prescription and over-the-counter, have risks as well as benefits. Think it through and work together with your doctor, pharmacist, and other health care professionals to better manage the benefits and risks of your medicines.

Speak up. Ask questions. Find the facts. Evaluate your choices. Read the label.
www.fda.gov/cder/drug or call 1-888-INFO-FDA



What are you adding to the mix?



Prescription and over-the-counter medicines don't always mix well with each other. Dietary supplements (including vitamins and herbs) and some foods and beverages can cause problems with your medicines. In fact, every time you add one more product, the chance of unwanted side effects increases.

Tell your doctor, pharmacist or other health care professional everything you are using, and *before* you add something new to the mix. Your health professionals can help you with what mixes well—and what doesn't.

Speak up
 Ask questions
 Find the facts
 Evaluate your choices
 Read labels



You have a hand in your health...

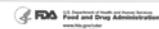


with the safe and effective use of your medicines.

When you use your medicines as directed, you can minimize their safety and effectiveness. But if your treatment plans don't fit your schedule, lifestyle or habits, following it can be hard. Other concerns important to you, such as cost, convenience, and side effects, can make it even harder.

Speak up
 Ask questions
 Find the facts
 Evaluate your choices
 ...with your health care professionals

Have a hand in your health decisions. Together with your health care professionals, agree on a medicine treatment plan that works for you.



Risk Management Print Public Service Ads

**Aspirin
 for Reducing Your
 Risk of Heart Attack
 and Stroke:**

**KNOW THE
 FACTS**

Aspirin therapy



Before Using Aspirin to Lower Your Risk of Heart Attack or Stroke, Here is What You Should Know

Only a health professional can safely decide if the regular use of aspirin to prevent a heart attack or stroke is right for you.

Aspirin. It's often thought of as one of those medicines over-the-counter that you're told on for pain to fight pain, swelling, headache and so. Now you're hearing that it can also lower your risk of a heart attack, or kinds of strokes and other very specific heart and blood vessel diseases, or help not use as aspirin a day? No need to bother your health professional with questions about something so simple, right? Wrong. Although aspirin seems like a quick and easy solution to any pain you might have, it's not simple as you think.

We're using aspirin to lower your chance of a heart attack or clot-related stroke and you haven't talked with a health professional about it, read on. Information here could help you avoid risks and stay healthy.

been about one hundred years since aspirin was created, and so that time we played a major role in treating headaches, fevers, minor aches and pains millions of people. Now there are studies that show it is also helpful in reducing the chance of a heart attack, clot-related stroke, and for increasing blood flow to the heart or brain in people with evidence of poor circulation.

If health professionals agree that long-term aspirin use to prevent a heart attack or stroke is healthy people to consider. If you are using aspirin to reduce the risk of a heart attack and stroke and you have not yet talked with a health professional about it, you may be getting your health at risk. You should ONLY use aspirin daily under the guidance of a health professional.

Visit www.fda.gov or call toll-free 1-888-INFO-FDA



TAKING ASPIRIN DAILY FOR YOUR HEART HAS BENEFITS AND RISKS



TALK TO YOUR DOCTOR FIRST.

Taking aspirin for a few days at a time to relieve pain or reduce fever is fine. But if you're taking it for weeks, months or even years to prevent a heart attack or stroke without guidance from your doctor, you could be doing your body more harm than good.

Only aspirin use has been shown to reduce the risk of a second, nonfatal stroke, but only in people for whom the health benefits outweigh the risks.

Talk to your doctor first before you begin taking aspirin to reduce your risk of heart attack or stroke. Only your doctor can tell you if you are a candidate for long-term aspirin therapy, and can then prescribe the correct dose and type of aspirin that is right for you.

For more information on how to safely reduce your risk of heart attack or stroke with aspirin, visit our web site at www.fda.gov or call toll-free 1-888-INFO-FDA.

FDA This message is brought to you as a public service of the U.S. Food and Drug Administration's Center for Drug Evaluation and Research.

"Please, care enough."



Such happy, healthy babies.

When their moms thought they might be pregnant – and after they knew they were – they always read the labels on any medicines and supplements before they took them. They wanted to make sure what they took for themselves was also safe for their babies. Now they are breast-feeding and they know anything they take – their babies take, too.

Talk to your doctor and care enough to read the label.

A message from
Council on Family Health
www.cfinfo.org

FDA U.S. Food and Drug Administration
www.fda.gov



Pregnancy and Drug Use



Take Action To Stop Drug Interactions.
 Read the medicine label.

A message from the
Council on Family Health
 and the **U.S. Food and Drug Administration**

For more information on how to prevent drug interactions, please visit the Council on Family Health at www.cfinfo.org

Drug Interactions

Using acetaminophen safely

Draft

Why is it important to know that all these contain the same active ingredient?



It could save your life.

Acetaminophen (APAP) is an active ingredient found in more than 600 over-the-counter and prescription medicines, such as pain relievers, cough suppressants and cold medications. It is safe and effective when used correctly, but taking too much can lead to liver damage, and even death. Different medicines contain different amounts, so read and follow dosage directions carefully. And don't take more than one acetaminophen product a day without first speaking to a health care professional. To learn more, call 1-888-INFO-FDA or visit www.fda.gov/cder. **Know the active ingredients in your medicines.**

FDA
 U.S. Department of Health and Human Services
 Food and Drug Administration

Antibiotic Resistance

DRAFT

Preserve a Valuable Resource



Antibiotics are precious weapons in your medical arsenal, but they are not cure-alls for all that ails your patients. Let us help you keep antibiotics potent, valuable resources your patients can count on. Contact FDA for "Antibiotics: Preserving a Valuable Resource" a concise, easy-to-read leaflet that will help patients say "no" to antibiotic misuse.

1-800-XXX-XXXX or www.fda.cder.com



U.S. Food and Drug Administration
Center for Drug Evaluation and Research



Snort. Sniffle. Sneeze.
No antibiotics please.

**Treat colds and flu with care.
Talk to your doctor.**

As a parent, you want to help your child feel better. But antibiotics aren't always the answer. They don't fight the viruses that cause colds and flu. What will? Fluids and plenty of rest are best. Talk to your doctor. Find out when antibiotics work – and when they don't. The best care is the right care.



Get Smart.
Know when antibiotics work.



Driving and Sedating Drugs

DRIVING?

Check ALL of Your Medicine Labels BEFORE YOU HIT THE ROAD

When Using This Product...

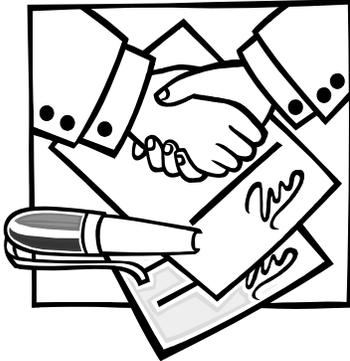
- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery



NHTSA
National Highway Traffic Safety Administration

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION ■ U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES ■ FOOD AND DRUG ADMINISTRATION

Partnerships...some examples



American Society of Health-System Pharmacists

AARP

National Council on Patient Info. and Education

Health Insurance Industry (e.g. BCBS)

National Association of Boards of Pharmacy

National Association of Chain Drug Stores

National Community Pharmacists Association

National Consumers League

Asthma and Allergy Foundation of America

Council on Family Health

Center for Substance Abuse Treatment

National Institute on Aging

American Pharmaceutical Association

National Patient Safety Foundation

Consumer Healthcare Products Association



CDER's Drug Safety Messages

- Medicines are safe only to the extent that they are used properly
- Communication between health care providers and patients (or their caregivers) is vital to drug safety
- Patients have a role in decision-making



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