

FDA Web-based Drug Information

Dr. Annetta L. Cheek
Plain Language Action and
Information Network

- I will focus on the website
- My colleague, Dr. Susan Kleimann, Center for Plain Language, will comment on specific documents.

I decided to visit the site as a consumer might. What follows is my record of my own thought processes.

First let's look at the homepage.



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- December 1. Amgen, Ortho Biotech and FDA notify healthcare professionals of revision to the prescribing information for Epogen and Procrit. [MedWatch Safety Info.](#)
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Professional Sheets for Alemtuzumab (marketed as Campath). [Campath Info.](#)

- November 30. MBI Distributing, Inc., an over-the-counter drug manufacturer of eye drops and other products, will cease manufacturing and distributing drugs until it corrects manufacturing deficiencies and other violations. [MedWatch Safety Information](#)

- November 29. Prescription Drug User Fee Act (PDUFA) White Paper: [Adding Resources and Improving Performance in FDA Review of New Drug Applications](#)

- November 29. CDER rescinds the November 18, 2005 approval of Kali Laboratories' ANDA 76-506 for Ondansetron Orally Disintegrating Tablets, 4 mg and 8 mg. [More Information](#)

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Safety Alerts for FDA Regulated Products

Main FDA number: 1-888-INFO-FDA (1-888-463-6332)
Drug Information Number: 301-827-4570 (8:00 am - 4:30 pm Eastern Time)

Page Last Updated: December 1, 2005

My first observation was that it was a long, complex homepage. I had to scroll. There were many different entry points I might pick to start looking for drug information, and I had no idea which was the best one.

I also wondered what CDER was
– the term was all over the site.



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But I decided it didn't matter, I didn't really care. This was just "background noise."

So then I decided to look for information about risks, since that's what you are most interested in.



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FDA is launching a new program to make drug safety information available to you in an easily accessible format. Because patients are taking a more active role in their healthcare, we want to make safety information available about the medicines they are using. We believe that patients, their healthcare professionals, and other consumers will find the information we are providing useful in their prescribing and treatment decisions.

Our Drug Safety Initiative has the following components:

- [Drug safety information located together in a new web location](#)
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- Federal Register Notice of Availability -- Draft Guidance for Industry on the Food and Drug Administration's "Drug Watch" for Emerging Drug Safety Information [[PDF](#)] [[HTML](#)] (5/10/2005)
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At that point, I decided the website had some problems, so I decided to look for more general information about drugs – what I'd want if a doctor recommended a drug to me and I wanted to check it out.



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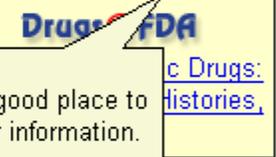
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Quick links are often a good place to start looking for popular information.

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- Drug approval letters, labels, and review packages

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This alphabetized list looked promising, so I decided to try it.

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Overview

Drug Name	BACITRACIN
Active Ingredient(s)	<ul style="list-style-type: none"> • BACITRACIN
Dosage Form(s) and Strength(s) Available	<ul style="list-style-type: none"> • INJECTABLE; INJECTION:10,000 UNITS/VIAL ;50,000 UNITS/VIAL • OINTMENT; OPHTHALMIC:500 UNITS/GM • OINTMENT; TOPICAL:500 UNITS/GM • POWDER; FOR RX COMPOUNDING:5,000,000 UNITS/BOT

This clearly isn't the kind of information I'm looking for.

Details about drugs are organized by FDA Application Number (NDA or ANDA or BLA).

[Click on a drug name or application number to view drug details:](#)

Drug Name and FDA Application Number	Dosage Form/Route	Strength	Marketing Status	Company
BACITRACIN (NDA # 061212)	OINTMENT; OPHTHALMIC	500 UNITS/GM	Prescription	ALTANA
BACITRACIN (NDA # 065116)	INJECTABLE; INJECTION	50,000 UNITS/VIAL	Prescription	AM PHARM PARTNERS
BACITRACIN	POWDER; FOR RX	5,000,000	Prescription	APOTHEKERNES



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Still can't find the answer?

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Contact CDER's Division of Drug Information.
druginfo@cder.fda.gov

1-888-INFO-FDA
1-888 463-6332 or (301) 827-4570

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5600 Fishers Lane, HFD-240
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There are lots of choices.

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I see why this wasn't the right "quick link" for me. It's under drug approvals - it's for industry. How was I to know? Are all of the homepage quick links for industry?

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This name looks promising but because it's under drug approvals I didn't try it.

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I don't want to deal with that page if I don't have to. So I go back to the homepage, again.



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This time I'll try the middle column. I don't really think I'm looking for information about safety, but since the more obvious choices didn't work out, I'll try this.



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Information for a drug will be in one of three different formats:

- ◆ **Patient Information Sheet** (with and without FDA Alerts)
- ◆ **Consumer Information Sheet** (for drugs approved since 1998. These will all be eventually converted to Patient Information Sheets)
- ◆ **Drug Information Page** (may include a Patient or Consumer Information Sheet, approval information, FDA press releases, questions and answers about a drug, and other related information)

*This Index **does not** include all FDA approved drugs, only those with Information Sheets and Pages. Please use [Drugs@FDA](#) to search for information on a drug not found in the Index.*

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A
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[Accutane](#) (isotretinoin)
[Aciphex](#) (rabeprazole)
[Actonel](#) (risedronate)
[AcuTect](#) (technetium Tc 99m apcitide)
[Actos](#) (pioglitazone)
[Advair Diskus](#) (Fluticasone propionate; Salmeterol xinafoate)
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[Agenerase](#) (amprenavir)
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F
[Factive](#) (gemifloxacin mesylate)
[Faslodex](#) (fulvestrant)
[Fentanyl](#)
[Ferlecit](#) (sodium ferric gluconate complex)
[Fluoxetine](#)
[Fluvoxamine](#)
[Foradil](#) (formoterol fumarate)
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R
[Radiogardase](#) (prussian blue)
[Ramelteon](#)
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[Raptiva](#) (efalizumab)
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[Reminyl](#) (galantamine)
[RenageL](#) (sevelamer)
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[Reyataz](#) (atazanavir)



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These are very confusing. What's the difference? How do I tell which of the items in the alphabetized list below is which type of document?

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[Frova](#) (frovatriptan succinate)
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R

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Well this may be the best place,
but the heading is confusing so
I'll try one more time on the
homepage, and if it doesn't work
out I'll come back here.



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- ◆ [Accutane \(isotretinoin\): A Letter to Consumers and Health Care Providers](#). Optional Format: [PDF](#). Dr. Janet Woodcock, CDER Director (1/9/2001)
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- ◆ [How To Obtain Domperidone](#) (5/18/2005)
- ◆ [Influenza Antiviral Drugs and Related Information](#) (12/27/2000).
- ◆ [Metered-Dose Inhalers \(MDIs\)](#) (updated 3/31/2005)

Over-the-Counter Drug Information

- ◆ [Over-the-Counter Drug Page](#). Information for consumers and industry about non-prescription drugs.

Drug Safety & Side Effects

- ◆ [Index to Drug-Specific Information](#) Provides links to Consumer, Patient, and Healthcare Professional Sheets, and more.
- ◆ [Accutane \(isotretinoin\): A Letter to Consumers and Health Care Providers](#). Optional Format: [PDF](#). Dr. Janet Woodcock, CDER Director (1/9/2001)
- ◆ [Adverse Events Reporting System](#) (Updated 8/7/2002)
- ◆ [AERS Electronic Submissions](#) (Updated 4/12/2001)
- ◆ [Clozapine Issue Paper](#) (2/1/2001)



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Index to Drug-Specific Information

Information for a drug will be in one of three different formats:

- ◆ **Patient Information Sheet** (with and without FDA Alerts)
- ◆ **Consumer Information Sheet** (for drugs approved since 1998. These will all eventually be converted to Patient Information Sheets)
- ◆ **Drug Information Page** (may include a Patient or Consumer Information Sheet, approval information, FDA press releases, questions and answers about a drug, and other related information)

This looks familiar! Isn't it the same information I found through the link to drug safety information?

*This Index **does not** include all FDA approved drugs, only those with Information Sheets and Pages. Please use [Drugs@FDA](#) to search for information on a drug not found in the Index.*

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A
[Abilify](#) (aripiprazole)
[Accutane](#) (isotretinoin)
[Aciphex](#) (rabeprazole)
[Actonel](#) (risedronate)
[AcuTect](#) (technetium Tc 99m apcitide)
[Actos](#) (pioglitazone)
[Advair Diskus](#) (Fluticasone propionate; Salmeterol xinafoate)
[Adderall](#) (amphetamine salts)
[Agenerase](#) (amprenavir)
[Aggrastat](#) (tirofiban)

F
[Factive](#) (gemifloxacin mesylate)
[Faslodex](#) (fulvestrant)
[Fentanyl](#)
[Ferlecit](#) (sodium ferric gluconate complex)
[Fluoxetine](#)
[Fluvoxamine](#)
[Foradil](#) (formoterol fumarate)
[Frova](#) (frovatriptan succinate)
[Fuzeon](#) (enfuvirtide)

R
[Radiogardase](#) (prussian blue)
[Ramelteon](#)
[Rapamune](#) (sirolimus)
[Raptiva](#) (efalizumab)
[Refludan](#) (lepirudin recombinant)
[Relenza](#) (zanamivir)
[Remeron](#) (mirtazapine)
[Reminyl](#) (galantamine)
[Renage](#) (sevelamer)
[Rescula](#) (unoprostone isopropyl)
[Reyataz](#) (atazanavir)



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A

- [Abilify](#) (aripiprazole)
- [Accutane](#) (isotretinoin)
- [Aciphex](#) (rabeprazole)
- [Actonel](#) (risedronate)
- [AcuTect](#) (technetium Tc 99m apcitide)
- [Actos](#) (pioglitazone)
- [Advair Diskus](#) (Fluticasone propionate; Salmeterol xinafoate)
- [Adderall](#) (amphetamine salts)
- [Agenerase](#) (amprenavir)
- [Aggrastat](#) (tirofiban)

F

- [Factive](#) (gemifloxacin mesylate)
- [Faslodex](#) (fulvestrant)
- [Fentanyl](#)
- [Ferlecit](#) (sodium ferric gluconate complex)
- [Fluoxetine](#)
- [Fluvoxamine](#)
- [Foradil](#) (formoterol fumarate)
- [Frova](#) (frovatriptan succinate)
- [Fuzeon](#) (enfuvirtide)

R

- [Radiogardase](#) (prussian blue)
- [Ramelteon](#)
- [Rapamune](#) (sirolimus)
- [Raptiva](#) (efalizumab)
- [Refludan](#) (lepirudin recombinant)
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- [Rescula](#) (unoprostone isopropyl)
- [Reyataz](#) (atazanavir)



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Adderall and Adderall XR (amphetamines) Information

FDA ALERT [08/2005] Health Canada Announces Return of Adderall to the Canadian Market.

Adderall will return to the Canadian market for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) (see alert of 02/09/05 below). The Canadian Product Monograph will be revised to include warnings about the misuse of Adderall and that Adderall generally should not be used in patients with structural cardiac abnormalities.

FDA ALERT [02/2005] Health Canada Suspends Marketing of Adderall

Health Canada has suspended marketing of Adderall XR products from the Canadian market due to concern about reports of sudden unexplained death (SUD) in children taking Adderall and Adderall XR. SUD has been associated with amphetamine abuse and reported in children with underlying cardiac abnormalities taking recommended doses of amphetamines, including Adderall and Adderall XR. In addition, a very small number of cases of SUD have been reported in children without structural cardiac abnormalities taking Adderall. At this time, FDA cannot conclude that recommended doses of Adderall can cause SUD, but is continuing to carefully evaluate these data.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

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- ◆ **Patient Information Sheet** [[PDF](#)] or [[HTML](#)]
- ◆ **Healthcare Professional Information**
 - Healthcare Professional Sheet [[PDF](#)] or [[HTML](#)]
 - [Prescribing Information](#)  (Adderall Label)

Other Information

- ◆ [Public Health Advisory for Adderall and Adderall XR](#)
- ◆ [FDA Statement on Adderall](#)
- ◆ [Regulatory History of Adderall from Drugs@FDA](#)

[Report Adverse Events to MedWatch](#)

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Date created: February 9, 2005; updated September 23, 2005

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Date created: February 9, 2005; updated September 23, 2005



Patient Information Sheet

Adderall and Adderall XR Extended-Release Capsules

This is a summary of the most important information about Adderall and Adderall XR. For details, talk to your healthcare professional.

FDA ALERT [08/05] Health Canada Announces Return of Adderall to the Canadian Market.

Adderall will return to the Canadian market for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) (see alert of 02/09/05 below). The Canadian Product Monograph will be revised to include warnings about the misuse of Adderall and that Adderall generally should not be used in patients with structural cardiac abnormalities.

FDA Alert [02/05] Health Canada Suspends Marketing of Adderall

Health Canada has suspended marketing of Adderall products from the Canadian market due to concern about reports of sudden unexplained death (SUD) in children taking Adderall. SUD has been associated with

- Overactive thyroid
- Glaucoma
- A history of drug abuse

Never take Adderall if you are taking a drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days.

Taking Adderall close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- High body temperature
- Coma
- Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxid), and other brands.

What Are The Risks?

- **Sudden deaths:** See FDA Alert.
- **Abuse potential:** See Warning.
- **Worsening mental illness (psychosis):** Adderall may make symptoms of existing mental illness worse.

FDA Alert [02/05] Health Canada Suspends Marketing of Adderall

Health Canada has suspended marketing of Adderall products from the Canadian market due to concern about reports of sudden unexplained death (SUD) in children taking Adderall. SUD has been associated with amphetamine abuse and reported in children with underlying cardiac abnormalities taking recommended doses of amphetamines, including Adderall. In addition, a very small number of cases of SUD have been reported in children without structural cardiac abnormalities taking Adderall. At this time, FDA cannot conclude that recommended doses of Adderall can cause SUD, but is continuing to carefully evaluate these data.

Adderall labeling contains a serious warning about the potential for abuse.

WARNING: ABUSE POTENTIAL

Amphetamines have a high potential for abuse. Taking amphetamines for long periods of time may lead to drug addiction. Particular attention should be paid to the possibility of people obtaining amphetamines for non-therapeutic use or distribution to others.

Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events.

What Is Adderall XR?

What Are The Risks?

- **Sudden deaths:** See FDA Alert.
- **Abuse potential:** See Warning.
- **Worsening mental illness (psychosis):** Adderall may make symptoms of existing mental illness worse.
- **Possible decreased growth and weight loss:** Adderall may decrease growth and cause weight loss. Children who take it for a long time should have their growth and body weight measured regularly.
- **Increased tics:** Adderall may worsen tics and Tourette's disorder.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because your baby may be premature or have a low birth weight. Also, your baby may show withdrawal symptoms, such as agitation and drowsiness.
- **Breast feeding:** Do not breast feed while taking Adderall because it can pass into your breast milk.
- **Other side effects** include loss of appetite, difficulty sleeping, dry mouth, headaches, and mood changes.
- **Tell your healthcare professional** about any medical conditions you have in addition to those already mentioned in this information sheet.

Are There Any Interactions With Drugs or Foods?

- Adderall may interact with other medicines. These interactions can cause serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially:

So what's my overall impression
of the CDER website?

Health information on the site is hard to navigate

- Pages are too complex
- Lists are too long
- Similar (but not identical) material occurs in multiple places

- It's impossible to tell, without opening a link, what audience a document addresses
- Some webpages and even some documents have multiple audiences
- There is no one place an audience can go to get all their information

If I were really trying to get information about drugs, I'd probably go to some other site that's easier to use.



Prescription Drug Information for Consumers & Professionals

- Home
- New Drugs
- Latest News
- Drug Interactions
- Pill Identification
- Images
- Forum

Drugs.com - prescription drug and medicine information available on over 24,000 approved medications and pharmaceuticals, including side effects and drug interactions.

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BEFORE



AFTER



Drug Information

Find information about more than 10,000 prescription and over-the-counter medications.

Enter a medication:

The drug information is not intended to cover all possible uses, directions, precautions, drug interactions or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the medicines you are taking or would like more information, check with your doctor, pharmacist or other healthcare professional.



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DRUGS & SUPPLEMENTS

Drug Information

Dec 3, 2005

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- [N-Nm](#) | [Nn-Nz](#) | [O](#) | [P-Pm](#) | [Pn-Pz](#) | [Q-R](#) | [S-Sm](#) | [Sn-Sz](#) | [T-Tm](#) | [Tn-Tz](#) | [U-W](#) | [X-Z](#) | [0-9](#)

Search: Enter a drug name



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Look up herb, vitamin and other supplement information from Natural Standard.

Browse: Find your supplement by first letter

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- Slim down your site – get rid of information no customer wants
- Get input from customers in multiple ways – web trends, ACSI survey, focus groups, usability tests

- Give each customer group an easy-to-find destination; include links to all their information there
- Don't make a visitor open a link to find out what's at the link
- Write each document and each page for ONE AUDIENCE only

Thanks for the opportunity to speak to you. Giving the public this opportunity to comment is a great step. If PLAIN can help you, please contact us through your FDA representative, Joanne Locke.