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.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

FDA NEWS

Unapproved Nitroglycerin Sublingual Tablets

The FDA has ordered the manufacturer and distributor of generic nitroglycerin sublingual tablets to stop producing and marketing their unapproved products. In letters to **Kona, Inc.** and **Glenmark Generics**, the agency ordered the firms to stop manufacturing the products within 90 days, and cease distribution of existing product within 180 days. This action is a result of the Unapproved Drug Initiative, begun in 2006 in an effort to remove from the market those drugs which have never received FDA approval. There is currently one FDA-approved nitroglycerin sublingual tablet on the market: Pfizer's **Nitrostat**. Since this action is **not** a recall, existing stock on pharmacy shelves may still be dispensed. The NDCs of the unapproved products are listed below:

- NTG 0.3 mg bottle of 100: 68462-0145-01
- NTG 0.4 mg bottle of 100: 68462-0146-01
- NTG 0.4 mg pkg of 4 x 25: 68462-0145-45
- NTG 0.6 mg bottle of 100: 68462-0147-01

FDA Warning on High-Dose Zocor: The FDA has notified healthcare professionals of an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication **Zocor** (simvastatin). The warning is based on data from the SEARCH trial which compared patients taking 80mg of Zocor to patients taking 20 mg. Patients in the high-dose group experienced more cases of myopathy (52 vs. 1) and more cases of rhabdomyolysis (11 vs. 0). The agency also reiterated the dosing limitations for Zocor when given with other drugs, which appears in the current product labeling:

Do not use simvastatin with the following:

- Itraconazole, Ketoconazole
- Erythromycin, Clarithromycin, Ketek
- HIV Protease Inhibitors
- Nefazodone

Do not use more than 10 mg of simvastatin:

- Gemfibrozil
- Cyclosporine
- Danazol

Do not use more than 20 mg of simvastatin:

- Amiodarone
- Verapamil

Do not use more than 40 mg of simvastatin

- Diltiazem

Cozaar Generic: Teva Pharmaceuticals expects to start shipping **losartan** by the end of April. Expect insurance companies to jump on this and start making other ARBs non-formulary. Physicians wishing to switch patients from a brand-name ARB to losartan may be asking pharmacists for information on equivalent doses for hypertension. A review of published comparison studies and institutional formularies yielded the following conversion chart, though not all sources agree and, since individual response may vary, patients should be monitored after any change in therapy:

Losartan	50 mg	100 mg
Atacand	8 mg	16 mg
Avapro	150 mg	300 mg
Benicar	10 mg	20 mg
Diovan	80 mg	160 mg
Micardis	40 mg	80 mg
Teveten	600 mg	800 mg

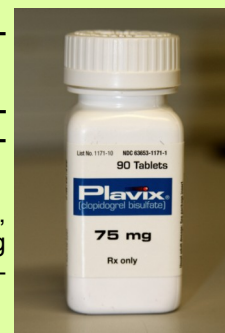
Kapidex Name Change: The FDA has approved a name change for the proton pump inhibitor **Kapidex** (dexlansoprazole), due to reports of dispensing errors involving drugs with similar names, including **Casodex** (bicalutamide) and **Kadian** (morphine sulfate). The new name for Kapidex will be **Dexilant**. The renamed product will have a new NDC number and is expected to be available in late April.

FDA Warns of Reduced Effectiveness of Plavix in Some Patients

The FDA has issued a drug safety communication regarding the reduced effectiveness of **Plavix** (clopidogrel) in patients who are poor metabolizers of the drug. Plavix is a prodrug which is converted to an active metabolite primarily by the CYP2C19 enzyme. It has been estimated that between 2 and 14% of the population are poor metabolizers due to alleles of CYP2C19 that have no functional metabolism of Plavix. Published reports indicate that people of African and Asian descent are at greater risk for poor metabolizer status. A **black box warning** has been added to the Plavix label which will include information to:

- **Warn about reduced effectiveness in patients who are poor metabolizers of Plavix. Poor metabolizers do not effectively convert Plavix to its active form in the body.**
- **Inform healthcare professionals that tests are available to identify genetic differences in CYP2C19 function.**
- **Advise healthcare professionals to consider the use of other antiplatelet medications or alternative dosing strategies for Plavix in patients identified as poor metabolizers**

This warning comes on the heels of another recent label change to Plavix, which advised against the concomitant use of CYP2C19 inhibitors, including **Prilosec** (omeprazole), **Nexium** (esomeprazole), **Intelence** (etravirine), cimetidine, fluconazole, fluoxetine, fluvoxamine, ketoconazole, and voriconazole.



MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

PPIs and the Preferred Drug Program

In light of recent changes in the market involving proton pump inhibitors (PPIs), the Department of Health has issued a clarification of which agents are covered and which require prior authorization.

Covered PPIs

Nexium (capsule)
Omeprazole OTC
Prevacid OTC
Prevacid Rx (capsule)
Prilosec OTC

PPIs Requiring Prior Authorization

Aciphex
Kapidex (Dexilant)
Lansoprazole
Nexium Packet
Omeprazole Rx
Pantoprazole
Prevacid Packet, Solutab
Prilosec Rx
Protonix

Oral Anti-Virals and the Preferred Drug Program

The department has also distributed a reminder that the new generic for **Valtrex** (valacyclovir) is **not** covered under the Preferred Drug Program. The coverage for oral anti-virals (non-HIV) is as follows:

Covered Oral Anti-Virals

Acyclovir
Valtrex

Oral Anti-Virals Requiring Prior Authorization

Famvir
Famciclovir
Valacyclovir
Zovirax

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

The practice of pharmacy is highly regulated by local, state, and federal agencies. When filling prescriptions, pharmacists must follow statutes and regulations overseen by the Education Department and the Board of Pharmacy, the Department of Health and the Bureau of Narcotic Enforcement, the Food and Drug Administration, Drug Enforcement Administration, and the Centers for Medicare and Medicaid Services. This is in addition to local Department of Consumer Affairs, which may arrive at any time to test your balance and check your Plan B stock! It seems appropriate, then, to always have handy a list of contact numbers for the various agencies involved should a question arise regarding the interpretation of the rules and regulations governing the practice of pharmacy.

NEW YORK STATE CONTACTS

State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000
Phone: (518) 474-3817 ext. 130
Fax: (518) 473-6995
email: pharmbd@mail.nysed.gov

Bureau of Narcotic Enforcement
433 River Street, Suite 303
Troy, New York 12180-2299
Phone: (866) 811-7957
Fax: (518) 402-0709
email: narcotic@health.state.ny.us

Medicaid Program
Claims: 800-343-9000
Prior Approval: 800-342-3005
Pharmacy Policy: 518-486-3209
Fraud Hotline: 877-873-7283
Medicaid Help Line: 800-541-2831

EPIC Program
Pharmacy Help Line: 800-634-1340

FEDERAL CONTACTS

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
Phone: (888) INFO-FDA (463-6332)
Website: www.fda.gov

Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, Virginia 22301
Phone (NY Office): (212) 337-3900
Website: www.usdoj.gov/dea
To Order 222 Forms: (800) 882-9539

New York Mailing Address
(For forwarding completed "reverse" 222 forms from returns):
Drug Enforcement Administration
New York Field Division
99 Tenth Avenue
New York, New York 10011

Medicare Part D Program
Phone: (800) MEDICARE
(800) 633-4227

REVIEW OF TOPICAL TESTOSTERONE THERAPY

It Has Been Estimated that between 5 and 13 million American men suffer from low testosterone levels, and that only about 5% of them seek treatment. Hypogonadism can result from a number of conditions, and can be classified as primary (testicular), secondary (hypothalamic-pituitary), or mixed. Aging plays a major role, as testosterone production decreases by 1% per year beginning at about age 30. Levels below 300 ng/dL are considered abnormal and the initial treatment of choice is the application of some form of transdermal testosterone (see below), which yields fewer side effects than oral dosage forms and more consistent blood levels than injectable forms. Below is a review of currently available topical testosterone products.

FDA Black Box Warning

Warning: Secondary Exposure To Testosterone

- Virilization has been reported in children who were secondarily exposed to testosterone gel
- Children should avoid contact with any unwashed or unclothed application sites in men using testosterone gel
- Healthcare providers should advise patients to strictly adhere to recommended instructions for use

Special Rules for N.Y State

Although Schedule III federally, testosterone products are **Schedule II** in New York State. Accordingly, the following applies to prescriptions for topical testosterone:

- Prescriptions are **never refillable**
- Prescriptions should be maintained **in the C-II file**
- Up to a six month supply may be dispensed if the prescriber indicates condition code "F" on the prescription

ANDROGEL Packets

Strengths Available: 1%

- 2.5 gm packets which contain 25 mg testosterone to deliver 2.5 mg per 24 hours
- 5 gm packets which contain 50 mg testosterone to deliver 5 mg per 24 hours



Counseling Points: Apply at the same time each day (preferably in the morning) to clean, dry, intact skin of the shoulders, upper arms, and/or abdomen (areas that will be covered by a short-sleeve T shirt to prevent transfer, but let dry a few minutes before dressing). Do not apply to penis or scrotum. Wash hands thoroughly after application. Discard used packet in trash out of the reach of children to avoid accidental exposure.

ANDROGEL Pump

Strengths Available: 1%

- Package contains 2 X 75 gm pumps. Each 75 gm pump dispenses 60 metered 1.25 gm doses (total package delivers 120 actuations)
- **Counseling Points:** Same as AndroGel Packets.



AndroGel Pump Dosing Chart

Prescribed Daily Dose	Number of Pump Actuations
5 gm	4 (once daily)
7.5 gm	6 (once daily)
10 gm	8 (once daily)

TESTIM Tubes

Strengths Available: 1%

- 5 gm tubes which contain 50 mg testosterone to deliver 5 mg per 24 hours



Counseling Points: Apply at the same time each day (preferably in the morning) to clean, dry, intact skin of the shoulders and/or upper arms (areas that will be covered by a short-sleeve T shirt to prevent transfer, but let dry a few minutes before dressing). Rub the gel onto your skin for several seconds until the gel is dry. Do not apply to penis, scrotum, or abdomen. Wash hands thoroughly after application. Wait at least 2 hours after applying Testim before showering or swimming to make sure Testim is absorbed into your body. Discard used packet in trash out of the reach of children to avoid accidental exposure.

ANDRODERM Patches

Strengths Available: see below

- 2.5 mg/day Transdermal System
- 5 mg/day Transdermal System



Counseling Points: Apply Androderm patch at the same time each evening, between 8:00 PM and Midnight. Replace patch every 24 hours. Only apply Androderm to a clean, dry area of your back, abdomen, thighs or upper arms. Never apply a patch to your genitals or onto skin areas with open sores, wounds, or irritation. Avoid application over bony areas, such as the upper shoulder and upper hip. Change application sites regularly to avoid irritation. Contact with water, such as showering or swimming, will not affect the patch. If a patch falls off before noon, replace it with a fresh patch. If it falls off later in the day, do not replace it until you apply a fresh patch that evening.



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Can prescriptions for Subutex (buprenorphine) and Suboxone (buprenorphine/naloxone) be refilled?

Yes. Subutex and Suboxone are Schedule III controlled substances and, as such, may be refilled, if authorized by the prescriber, up to a maximum of 5 times within six months from the date the prescription was signed (section 80.69(g) of the Rules and Regulation on Controlled Substances). Buprenorphine was the first drug approved for office-based treatment of opioid dependence. When prescribed for this indication, the prescription must contain both the physician's DEA number and his or her DATA2000 unique identification number, which begins with an "X". These unique ID numbers can be verified by calling **1-866-287-2728** or visiting the SAMHSA website at www.buprenorphine.samhsa.gov. Prescriptions written for off-label use, such as for the treatment of pain, do not require the "X" number, but should be verified by the pharmacist filling the prescription.

I know that prescriptions for controlled substances written with an appropriate "condition code" for a 90-day supply may contain 1 refill. Occasionally we receive a "coded" prescription written for a 60-day supply rather than 90-day supply. In such cases, is the prescriber permitted to write for 2 refills?

No. According to section 80.69(g) of the Rules and Regulations on Controlled Substances, "coded" prescriptions written for a quantity in excess of a 30-day supply may be refilled only once. Also, keep in mind that prescriptions written for Schedule II drugs, including anabolic steroids, and prescriptions written for benzodiazepines may not be refilled in New York State. For an explanation of the "condition codes," visit our website at: www.prnnewsletter.com

GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:

askprn@prnnewsletter.com








PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that Dr. James W. Black, who discovered two of the most important breakthrough drugs of the twentieth century, died earlier this month at the age of 85? The Scottish-born Nobel Prize-winning pharmacologist and his team developed the first beta blocker, propranolol, in the mid-1960s, which revolutionized the treatment of cardiovascular disease. Later, Dr. Black's research led to the discovery of the first H-2 receptor blocker, cimetidine, which greatly reduced the number of surgeries performed to treat ulcers. It is fair to say that Dr. Black, through his work, improved the health and extended the lives of millions of people.

PHARMACY FUN

For no particular reason, it's rebus time again! The first reader to correctly identify the 3 brand-name drugs represented below will receive a custom-printed PRN binder. Send your answers to puzzle@prnnewsletter.com

1.  + "F" + 
2.  +  + "N"
3.  +  + 

Answers to last month's **PHARMACY FUN**:

1. Lovenox 2. Flovent

Photographs by James Murphy