P.R.N.

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What's Inside…

FDA NEWS

Recent FDA actions and approvals include:

Zolpimist Oral Spray has been approved for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Zolpimist is an oral spray version of the sedative hypnotic agent Zolpidem. Due to its rapid onset of action, Zolpimist should be used immediately before bedtime and patients should be prepared to get a full 7 to 8 hours of sleep. The manufacturer, NovaDel, has begun development of a lower dose version of Zolpimist for treatment of middle-of-the-night-awakenings.

Latisse (bimatoprost) is the first FDA-approved treatment for hypotrichosis of the eyelashes. Latisse, which has the same active ingredient as **Lumigan**, increases the length, thickness, and darkness of eyelashes in as little as eight weeks, with full results in 16 weeks. Latisse is applied nightly directly to the skin of the upper eyelid margin at the base of the eyelashes using the accompanying sterile applicators. Like Lumigan, Latisse can cause a permanent darkening of the iris. The most common adverse effects seen in clinical trials were eye pruritis, conjunctival hyperemia, and skin hyperpigmentation.

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New Fibromyalgia Treatment: The FDA has approved Forest Pharmaceuticals' **Savella** (milnacipran) for the management of fibromyalgia. Previously, **Cymbalta** and **Lyrica** were the only FDA-approved drugs for fibromyalgia. Savella is a potent inhibitor of neuronal norepinephrine and serotonin reuptake. In clinical trials, the most common adverse effects reported were nausea, headache, constipation, and dizziness. Savella is contraindicated in patients taking monoamine oxidase inhibitors and in patients with uncontrolled narrow-angle glaucoma. Blood pressure and heart rate should be monitored prior to initiating treatment and periodically thereafter. The recommended dose of Savella is 50 mg twice a day, with or without food (although food may improve tolerability of the drug). Initially, dosing should be titrated according to the following schedule:

Day 1: 12.5 mg once
Days 2-3: 25 mg/day (12.5 mg twice daily)
Days 4-7: 50 mg/day (25 mg twice daily)
After Day 7: 100 mg/day (50 mg twice daily)

Dose may be increased to 200mg/day based on individual patient response.[1] Savella will be available in 12.5, 25, 50, and 100 mg tablets, as well as a 4-week titration pack. The manufacturer expects that Savella will be available in pharmacies by March, 2009.

DEA Fines Rite Aid: The Drug Enforcement Administration (DEA) has announced that the Rite Aid corporation has agreed to pay 5 million dollars in civil penalties to settle allegations of violations of the Controlled Substance Act (CSA). Rite Aid operates 4,915 stores in 31 states. The investigation, which began in 2004, centered on 53 Rite Aid pharmacies, including stores in New York, Pennsylvania, Maryland, Kentucky, and California. According to the DEA, the investigation revealed a pattern of CSA violations, including:

- Knowingly filling prescriptions for controlled substances (CS) that were not issued for a legitimate purpose
- Failure to notify the DEA in a timely manner of significant losses or thefts of CS
- Failure to maintain or to furnish to the DEA upon request records that are required to be kept under the CSA for a period of two years
- Failure to properly execute DEA forms used to ensure that the amount of Schedule II drugs ordered were actually received

In addition, accountability audits in 25 of the 53 pharmacies revealed significant shortages or surpluses of the most highly abused drugs, including oxycodone and hydrocodone.

CDC: This Year's Flu Virus Highly Resistant To Tamiflu (Oseltamivir)

The Centers for Disease Control and Prevention (CDC) has issued a health advisory regarding the 2008-09 Influenza season. Though the flu season has been mild thus far, the most common strain seen this year (Type A, subtype H1N1) has proven to be resistant to **Tamiflu** in 98% of cases. This strain is susceptible, however, to **Relenza** (zanamavir), **Amantadine**, and **Flumadine** (rimantadine). Amantadine and Flumadine are no longer recommended as monotherapy due to lack of activity against Type B influenza and resistance among Type A H3N2 strains. For patients suspected of being infected with H1N1 who cannot tolerate Relenza, a dry powder inhaler, the CDC recommends a combination of Tamiflu and Flumadine. Relenza is not recommended for use in patients with respiratory diseases, such as asthma or COPD, nor is it approved for children under the age of 7. The following table was adapted from a more complete version available from the CDC at: ***www. cdc.gov/flu***.

Rapid antigen or other laboratory test	Predominant virus(es) in community	Preferred medication(s)	Alternative combination
Not done or negative, but clinical suspicion for influenza	**H1N1** or **unknown**	**Relenza**	**Tamiflu** *and* **Flumadine**
Not done or negative, but clinical suspicion for influenza	**H3N2** or **Type B**	**Tamiflu** *or* **Relenza**	**None**

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Quantity Limits on Supplies

The New York State Medicaid Program covers many types of medical/surgical supplies. For each item, however, there is a maximum supply allowed per filling. In order to avoid unnecessary rejections, it is helpful to know the maximum allowable quantity for the most popular medical/surgical supplies:

Adult Diapers	**250**
Alcohol Wipes	**500**
Blood Glucose Strips	**250**
Enteral Formulas	**600***
Insulin Syringes	**200**
Lancets	**500**
Underpads, Disposable	**300**

*For enteral formulas, the maximum per prescription is 600 caloric units. A caloric unit is defined as 100 calories. For enteral formulas containing 250 calories per can (2.5 caloric units), the maximum allowed per prescription is 240 cans.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Changes and Additions to Controlled Substance Prescriptions

A common problem facing community pharmacists is the presentation of a prescription for a controlled substance which is missing legally required information. Additionally, there are often clinical, insurance coverage, or patient preference issues which require changes to be made to such prescriptions. In the past, many such additions and/or changes were prohibited and pharmacists were required to request new prescriptions in order to serve their patients. In order to facilitate proper patient care, the New York State Department of Health adopted regulations on May 19, 1999 that allow pharmacists to add or change certain information on controlled substance prescriptions, including those for C-II drugs. Sections 80.73(m) and (n) of the Rules and Regulations on Controlled substance state:

> **"When an official New York State prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature."**
>
> **"A practitioner may orally authorize a pharmacist to change information on an official New York State prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change."**

There are certain items which may *never* be added or changed for controlled substance prescriptions, and some items which *do not require* the prescriber's authorization. We have created an easy reference chart for pharmacists (see below).

N.Y. STATE REGULATIONS ON CHANGES TO CONTROLLED SUBSTANCE PRESCRIPTIONS

ADDITIONS TO CONTROLLED SUBSTANCE RX		CHANGES TO CONTROLLED SUBSTANCE RX	
Pharmacist may add *without* prescriber's authorization	**Pharmacist may add *with* prescriber's authorization**	**Pharmacist may change *without* prescriber's authorization**	**Pharmacist may change *with* prescriber's authorization**
• Patient's address • Patient's sex • Patient's age	• Prescriber's DEA # • Institution's DEA # • Drug strength • Directions for use • Maximum daily dose • Condition code	• Patient's address • Patient's sex • Patient's age	• Prescriber's DEA # • Institution's DEA # • Drug strength • Quantity • Dosage form • Directions for use • Maximum daily dose • Condition code
NEVER ADD		***NEVER CHANGE***	
Patient's name **Prescriber's signature** **Date written** **Drug name** **Quantity**		**Patient's name** **Prescriber's signature** **Date written** **Drug name**	

Feature Article..

INNOVATIONS IN INSULIN THERAPY

The Introduction Of Insulin in 1923 revolutionized the treatment of diabetes mellitus. For the first time there was a viable treatment for a disease first described in 1552 BC by the Egyptian physician Hesy-Ra. While many advances in purification and duration of action of insulin took place over the ensuing 70 years, it wasn't until 1996 that a series of truly novel insulin products became available. Starting with **Humalog** in 1996, there followed **Novolog** and **Lantus** in 2000, **Apidra** in 2004, and **Levimir** in 2005. These innovations coincided with an increasing use of insulin in the Type 2 diabetic population, which is now routinely placed on insulin therapy earlier in the course of the disease. Below is a quick review of the new insulin products, as well as a primer on use of the increasingly popular insulin pen devices.

	SHORT-ACTING ANALOGS			LONG-ACTING ANALOGS	
Brand Name (generic)	**Humalog** (insulin lispro)	**Novolog** (insulin aspart)	**Apidra** (insulin glulisine)	**Lantus** (insulin glargine)	**Levemir** (insulin detemir)
Onset of Action	**15 to 30 minutes**	**10 to 20 minutes**	**10 to 15 minutes**	**1.1 hours**	**0.8 to 2 hours**
Duration of Action	**3 to 6.5 hours**	**3 to 5 hours**	**3 to 5 hours**	**24 hours**	**12 to 24 hours**
Administration	**Inject within 15 minutes before or immediately after meals**	**Inject 5 to 10 minutes before meals**	**Inject within 15 minutes before or within 20 minutes after starting meal**	**Inject once daily at the same time each day**	**Inject once or twice daily (if once, give at evening meal or at bedtime)**
Compatibility	**Can be mixed with NPH (draw Humalog into syringe first)**	**Can be mixed with NPH (draw Novolog into syringe first)**	**Can be mixed with NPH (draw Apidra into syringe first)**	**Do not mix with other insulins**	**Do not mix with other insulins**
Room Temperature Stability (while in use)	**28 days**	**28 days**	**28 days**	**28 days**	**42 days**

Insulin Pen Devices: Use and Storage

Since the introduction of the original **NovoPen** in 1985, insulin pen devices have steadily increased in popularity. The original insulin pens were reusable, and though many such devices remain on the market (**NovoPen 3**, **HumaPen Memoir**, **HumaPen Luxura HD**), the newer , disposable pens are becoming the most popular choice among patients and physicians. Many of the insulin analogs discussed above are now available in pen form (**Humalog Pen**, **Humalog KwikPen**, **Novolog Flexpen**, **Lantus Solostar**, **Levemir Flexpen**). General instructions for use of disposable insulin pens follow:

- **Wash hands and check appearance of insulin. For cloudy insulins (NPH, Humalog Mix, Novolg Mix etc.) mix until uniform by rolling between palms 10 times then inverting up and down 10 times**
- **Attach a new disposable pen needle to pen (wipe rubber stopper with alcohol swab first)**
- **Perform an "air shot" by dialing in 2 units, holding pen upright, tapping cartridge to force any air bubbles to the top, then completely depressing push button until a drop of insulin appears at needle tip**
- **Dial in correct insulin dose, wipe injection site with alcohol swab, inject dose by depressing push button and holding for at least 5 seconds for Lilly products, 6 seconds for Novo Nordisk products, or 10 seconds for Lantus Solostar.**
- **Remove used pen needle and replace insulin pen cap or cover**

In-use disposable insulin pens should be stored at room temperature. Stability differs by product type:

Stability at Room Temperature (below 86° F)	**42 days**	**28 days**	**14 days**	**10 days**
Insulin Pen	**Levemir**	**Humalog Novolog Lantus**	**Novolog Mix**	**Humalog Mix**

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ASK PRN...

In a previous issue of *PRN* (Dec., 2007) you stated that coupons are acceptable for controlled substance prescriptions. Does this include Schedule II drugs?

Yes. Effective January 12, 2007, the Department of Health reversed its rule prohibiting the use of coupons for controlled substance prescriptions. Coupons and vouchers are now acceptable for use when accompanied by a valid prescription. This applies to all controlled substances, including C-II drugs.

In New York State, which prescription file (C-II or C-III-IV-V) should prescriptions for anabolic steroids (Androgel, Testosterone, etc.) be filed in?

Anabolic steroids are Schedule III federally, but Schedule II in New York. Therefore, such prescriptions filled in New York should be filed in the C-II prescription file. Benzodiazepines, while following C-II rules in New York, should still be filed in the C-III-IV-V file.

When a prescription is written for a 90-day supply of a controlled substance, with the proper condition code, can the prescription be refilled if indicated by the prescriber?

Yes. Prescriptions written for controlled substances in quantities exceeding a 30-day supply, with appropriate condition codes, may be refilled once within 6 months of the date the prescription was signed. This does not apply to C-II drugs, anabolic steroids, or benzodiazepines, which may never be refilled in New York State. In addition, if a prescription is written for more than 30, but less than 90 days (e.g., a 60-day supply), it may still only be refilled one time. For a complete explanation of condition codes, see the January, 2008 issue of ***PRN*** or visit out 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 the first person ever to receive an injection of insulin was a 14-year-old boy named Leonard Thompson? Thompson, a Type 1 diabetic, lay gravely ill in a Toronto, Ontario hospital in early 1922. At the time, the disease was often fatal within weeks to months, and the boy's life was saved by injections of bovine insulin extracted by Canadian scientists Banting, Best, Macleod, and Collip. Thompson lived for another 13 years after his initial treatment. In 1923, Eli Lilly and Company introduced the first commercially available insulin, eventually transforming diabetes from a terminal disease into a treatable chronic illness.

PHARMACY FUN

Flu season is upon us, and that got us to thinking about the remarkable number of prescription drugs with names that start with the letters F-L-U. How many can you name? (All answers are generic names) The first reader to send the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. **BZD for insomnia**
2. **Dopamine antagonist**
3. **The original SSRI**
4. **HMG-CoA reductase inhibitor**
5. **NSAID**
6. **Ophthalmic steroid**
7. **Nasal steroid**
8. **Oral candidiasis agent**
9. **BZD antidote**
10. **Steroid for hypotension**
11. **SSRI for OCD**
12. **Topical for actinic keratosis**

Answers to last month's **PHARMACY FUN**:
1. Valacyclovir 2. Fosamprenavir 3. Hydroxyzine 4. Imipramine 5. Levodopa 6. Valganciclovir 7. Cortisone 8. Carisoprodol 9. Codeine 10. Amitriptyline 11. Risperidone 12. Primidone 13. Fosphenytoin 14. Prednisone 15. Caffeine

References:
1. Savella [package insert]. New York, NY: Forest Laboratories, Inc.; January, 2009