

# AU InforMed

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## Key Inforbits

- New dose form and indication
- Lots of MedWatches
- Common contact allergens
- Tamiflu, expensive boondoggle?
- Web site bodyguard?
- Hammer theory

## **NEW DRUGS, and other related stuff ...**

**New Dose Form** ... The FDA approved the **selegiline transdermal system (EMSAM<sup>®</sup>)** developed by Somerset Pharmaceuticals; distributed by Bristol-Myers Squibb) on February 28, 2006. It is the first transdermal patch for the treatment of major depressive disorder in adults. EMSAM<sup>®</sup> is a monoamine oxidase inhibitor that has been shown to relieve depressive symptoms in patients with major depressive disorder.

FDA. FDA approves Emsam (selegiline) as first drug patch for depression. *FDA News* 2006 Feb 28; P06-31.

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01326.html> (FDA News)

[http://www.bms.com/cgi-](http://www.bms.com/cgi-bin/anybin.pl?sql=select%20PPI%20from%20TB_PRODUCT_PPI%20where%20PPI_SEQ=112&key=PPI)

[bin/anybin.pl?sql=select%20PPI%20from%20TB\\_PRODUCT\\_PPI%20where%20PPI\\_SEQ=112&key=PPI](http://www.bms.com/cgi-bin/anybin.pl?sql=select%20PPI%20from%20TB_PRODUCT_PPI%20where%20PPI_SEQ=112&key=PPI) (link to package insert)

**New Indication** ... On February 28, 2006, the FDA approved the use of rituximab (Rituxan<sup>®</sup> by Biogen Idec and Genentech) in combination with methotrexate to reduce signs and symptoms in adult patients with moderately-to-severely active rheumatoid arthritis (RA). Candidates for treatment are those who had an inadequate response to one or more tumor necrosis factor antagonist therapies. Rituxan<sup>®</sup> is the first treatment for RA that selectively targets immune cells known as CD20-positive B-cells.

<http://www.rituxan.com/> (Biogen web site)

**MedWatch** ... Four lots (379,975 vials) of **Cefazolin for Injection, USP**, 1 g/10 mL vials (Manufactured by Hanford Pharmaceuticals, distributed by Sandoz, Inc. and Watson Pharmaceuticals, Inc.) have been **recalled**. Certain lots of the active ingredient used to manufacture the product have been shown to contain microbial contamination (*Bacillus pumilus*, *Staphylococcus hominis*, *Propionibacterium acnes*, or *Micrococcus luteus*) which may pose a serious or life-threatening risk for some patients. Hospitals, clinics, and users should stop using the affected lots immediately. Read the complete MedWatch 2006 Safety summary, including a link to the firm's press release, at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Cefazolin>

**MedWatch** ... Safety-related drug labeling changes for December 2005 have been posted on the MedWatch website; it includes 26 drug products with safety labeling changes.

The Summary page --

[http://www.fda.gov/medwatch/SAFETY/2005/dec05\\_quickview.htm](http://www.fda.gov/medwatch/SAFETY/2005/dec05_quickview.htm)

-- provides drug names and a listing of the sections changed.

The Detailed view -- <http://www.fda.gov/medwatch/SAFETY/2005/dec05.htm>

-- includes sections/subsections changed and a description of new or modified safety information in the Contraindications, Boxed Warning, or Warnings sections. The full labeling may be accessed by clicking on the drug name in the detailed view.

**MedWatch** ...Actelion and the FDA notified healthcare professionals of changes to the **Tracleer<sup>®</sup> (bosentan)** prescribing information based on cases of hepatotoxicity reported. Bosentan is indicated for the treatment of pulmonary arterial hypertension. The notification underscored the need to continue monthly liver function monitoring for the duration of bosentan treatment and the need to adhere to the recommended dosage adjustment and monitoring guidelines described in the product labeling.

Read the complete MedWatch 2006 Safety summary, including links to the Dear Healthcare Professional letter, revised prescribing information and medication guide at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#Tracleer>

**MedWatch** - The FDA warned several manufacturers and distributors of **unapproved drugs containing steroids** that are marketed as dietary supplements and promoted for building muscle and increasing strength, that the products may cause serious long-term adverse health consequences in men, women, and children. These products claim to be anabolic and problems associated with anabolic steroids include: liver toxicity, testicular atrophy and male infertility, masculinization of women, breast enlargement in males, and short stature in children. Anabolic steroids are also associated with causing adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke. Consumers who have any of the following products should stop taking them and return them to their place of purchase:

- Anabolic Xtreme Superdrol- manufactured for Anabolic Resources LLC, Gilbert, AZ
- Methyl-1-P, manufactured for Legal Gear, Brighton, MI

Read the complete MedWatch 2006 Safety summary, including links to the FDA Press release and Warning Letters to manufacturers and distributors of illegal steroid products sold as dietary supplements at:

<http://www.fda.gov/medwatch/safety/2006/safety06.htm#steroids>

## **FROM THE MEDICAL LITERATURE ...**

**Common contact allergens** ... A new Mayo Clinic study reveals the most common causes of allergic contact [dermatitis](#). The top 10 are:

- Nickel (nickel sulfate hexahydrate) -- metal frequently encountered in jewelry and clasps or buttons on clothing
- Gold (gold sodium thiosulfate) -- precious metal often found in jewelry
- Balsam of Peru (myroxylon pereirae) -- a fragrance used in perfumes and skin lotions, derived from tree resin
- Thimerosal -- a mercury compound used in local antiseptics and in vaccines
- Neomycin sulfate -- a topical antibiotic common in first aid creams and ointments, also found occasionally in cosmetics, deodorant, soap and pet food
- Fragrance mix -- a group of the eight most common fragrance allergens found in foods, cosmetic products, insecticides, antiseptics, soaps, perfumes and dental products

- Formaldehyde -- a preservative with multiple uses, e.g., in paper products, paints, medications, household cleaners, cosmetic products and fabric finishes
- Cobalt chloride -- metal found in medical products; hair dye; antiperspirant; objects plated in metal such as snaps, buttons or tools; and in cobalt blue pigment
- Bacitracin -- a topical antibiotic
- Quaternium 15 -- preservative found in cosmetic products such as self-tanners, shampoo, nail polish and sunscreen or in industrial products such as polishes, paints and waxes

This study, presented Monday, March 6 at the American Academy of Dermatology annual meeting in San Francisco, confirmed that patch testing with a standard contact dermatitis series of substances is useful for identifying common contact allergens. Results from 3,854 patients over 5 years were analyzed (2001-2005). Allergen avoidance is the chief treatment for contact dermatitis, though at times corticosteroid creams are used to treat rashes. However, 3% of patients with contact dermatitis are allergic to the topical corticosteroids.

Davis M, et al. Top Ten Contact Dermatitis Allergens Identified in Mayo Clinic Study. Mayo Clinic press release. 2006 Mar 3.

<http://www.mayoclinic.org/news2006-rst/3268.html?rss-feedid=1>

### **Reviews of Note ...**

- DeZee KJ, Shimeall WT, Douglas KM, Shumway NM, O'Malley PG. Treatment of excessive anticoagulation with phytonadione (vitamin K). *Arch Intern Med.* 2006 Feb 27;166(4):391-397.
- Rogers RL, Martinez JP, eds. Emergencies in the outpatient setting: Part I. *Med Clin N Am.* 2006 Mar;90(2):275-390. [5 articles]
- Watkins PB, Seeff LB. Drug-induced liver injury: Summary of a single topic clinical research conference. *Hepatology.* 2005 Mar;43:618-31.
- Delacrétaç E. Supraventricular tachycardia. *N Engl J Med.* 2006 Mar 9;354(10):1039-51.
- Dalen JE. Aspirin to prevent heart attack and stroke: What's the right dose? *Am J Med* 2006 Mar;119(3):198-202.

### **FROM THE LAY LITERATURE about medicine ...**

**Post-marketing drug studies** ... are another category of “backlogged” at the FDA. According to an article, 65% of these post-market studies have yet to be started or are delayed. This equates to 797 out of 1,231 drug studies. Post-marketing surveillance studies are one way the FDA attempted to get new drugs on the market faster, accepting more preliminary results for initial approval. There are 54 manufactures involved, going back several years. While the FDA can pull a drug from the market if studies aren't completed, it appears there are some enforcement problems.

Dooren JC. Most post-market studies are listed as ‘pending’ by the FDA. *Wall Street Journal.com* 2006 Mar 3. Associated Press. 65% of promised drug studies pending. *Washington Post.com* 2006 Mar 4; p. A04.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/03/03/AR2006030301702.html?referrer=email>

**More Tamiflu®** ... The federal government is buying more Tamiflu® (oseltamivir by Roche) as a precaution against a “bird flu” pandemic. They have now ordered enough to treat 17.4 million people. The president’s goal is to have a stockpile sufficient to treat 25% of the population, roughly 75 million people. One wonders that if/when such a pandemic strikes, will the drugs be effective against that eventual strain?

Associated Press. More Tamiflu ordered for federal stockpile. *USA Today* 2006 Mar 1.

[http://www.usatoday.com/news/health/2006-03-01-tamiflu\\_x.htm](http://www.usatoday.com/news/health/2006-03-01-tamiflu_x.htm)

### **NEW RESOURCES in the DILRC ...**

- Allen LV Jr. *Allen’s Compounded Formulations*. Washington, DC: American Pharmacists Association, 2003.
- Trissel LA. *Trissel’s Stability of Compounded Formulations*. 3<sup>rd</sup> ed. Washington, DC: American Pharmacists Association, 2005.
- Tierney LM Jr, McPhee SJ, Papadakis MA, eds. *Lange 2006 Current Medical Diagnosis and Treatment*. 45<sup>th</sup> ed. NY: Lange Medical Books/McGraw-Hill, 2006.
- Kasper DL, Braunwald E, Fauci AS, Hauser SL, Longo DL, Jameson JL, eds. *Harrison’s Principles of Internal Medicine*. 16<sup>th</sup> ed. NY: McGraw-Hill, 2005.

### **TIMELY TOP TECH TIP ...**



**Web site bodyguards** ... “SiteAdvisor” is an add-on for Internet Explorer and Firefox attempts to interpret the relative safety of Web sites that show up in search results, from common search engines such as Google and Yahoo (in beta version). With SiteAdvisor search listings are accompanied by a small color-coded icon, such as the red "X" that comes up next to sites that have had reports of suspicious or malicious activity or a green check mark for all clear, and a couple in between. It also offers an explanation as to why it is so rated. Could be useful.

Krebs B. Exposing web addresses' hidden mischief. *Washington Post* 2006 Mar 5; p. F07.

<http://www.washingtonpost.com/wp-dyn/content/article/2006/03/04/AR2006030400208.html?referrer=email>



### **The last “dose” ...**

It is tempting, if the only tool you have is a hammer, to treat everything as if it were a nail.

-- Abraham H. Maslow [1908-1970], in *The Psychology of Science* [1966].



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