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FDA PRODUCT SAFETY NEWS

Danger of Skin Numbing Products (*Jan 16th, 2009*)

The U.S. Food and Drug Administration issued a Public Health Advisory to alert consumers, patients, health care professionals, and caregivers about potentially serious and life-threatening side effects from the improper use of skin numbing products. The products, also known as topical anesthetics, are available in over-the-counter (OTC) and prescription forms. (<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01947.html>)

FDA Issues Update to Safety Review on Cholesterol-Lowering Drugs (*Jan 8th, 2009*)

The U.S. Food and Drug Administration reaffirmed its position that elevated amounts of low-density lipoprotein (LDL), or “bad cholesterol,” are a risk factor for cardiovascular diseases such as heart attack, stroke and sudden death and that lowering LDL cholesterol reduces the risk of these diseases. FDA's comments are contained in an update to its Jan. 25, 2008, Early Communication describing the agency’s review of data from ENHANCE, a clinical trial comparing Zocor (simvastatin), a drug that lowers cholesterol production in the liver, to Vytorin, a drug that combines Zocor with another drug, Zetia (ezetimibe), which inhibits cholesterol absorption. (<http://www.fda.gov/bbs/topics/NEWS/2009/NEW01939.html>)

Salmonella Typhimurium Outbreak Update (*Jan 21st, 2009*)

FDA is conducting a very active and dynamic investigation into the source of the *Salmonella* Typhimurium outbreak. At this time, the FDA, the Centers for Disease Control and Prevention, and state partners have traced sources of *Salmonella* Typhimurium contamination to a plant owned by Peanut Corporation of America (PCA), which manufactures peanut butter and peanut paste that are both distributed to food manufacturers to be used as an ingredient in many commercially produced products. (<http://www.fda.gov/oc/opacom/hottopics/salmonellatyph.html>)

Source: FDA Information Update for Health Professionals (more at <http://www.fda.gov>)

BRAND (GENERIC) DRUG	RECENT UPDATES/ALERTS ON SELECTED DRUGS
Savella (milnacipran hydrochloride)	<p><u>New Drug Approval for Fibromyalgia (posted 1/16/2009)</u> Forest Laboratories and Cypress Bioscience received FDA approval on Savella, a selective serotonin and norepinephrine dual reuptake inhibitor, for the treatment of fibromyalgia. Savella is expected to be available in the pharmacies by March 2009.</p>
Seroquel XR (quetiapine fumarate)	<p><u>New Dosage Strengths Available (posted 1/12/2009)</u> Starting January 12th, 2009, Seroquel XR will be available in the 50mg and 150mg dosage strengths in addition to the already available 200mg, 300mg and 400mg dosage strengths. It is currently FDA-approved for treatment of schizophrenia and treatment of manic, depressive, and mixed episodes of bipolar disorder.</p>
AllerNase (triamcinolone acetonide)	<p><u>New Drug Approval for Allergic Rhinitis (posted 1/12/2009)</u> Collegium Pharmaceutical announces FDA approval of AllerNaze 50 mcg nasal inhaled steroid for the once-daily treatment of nasal symptoms associated with seasonal allergic rhinitis and perennial allergic rhinitis in adults and children 12 years and older. Allergic rhinitis is an inflammatory reaction of the nasal passages to allergens such as pollens (seasonal allergic rhinitis) or dust mites, animal dander and mold (perennial allergic rhinitis).</p>
Oral sodium phosphate products (OSP): Visicol, OsmoPrep	<p><u>OSP Nephropathy Risk (posted 12/11/2008)</u> Reports of acute phosphate nephropathy associated with the use of OSP products alarmed the FDA to require Salix, the manufacturer of Visicol and OsmoPrep, add a Boxed Warning and a Medication Guide to their product labeling. In addition, a post-marketing clinical trial will be conducted to assess the nephropathy risk associated with the use of these products. OSP is used for bowel cleansing prior to colonoscopy or other procedures. The FDA currently does not recommend high dose OTC laxative OSP products for bowel cleansing as they carry the same risks unless pursuant to prescription from a healthcare provider.</p>
Bisphosphonates: Alendronate (Fosamax, Fosamax Plus D), Etidronate (Didronel), Ibandronate (Boniva), Pamidronate (Aredia), Risedronate (Actonel, Actonel W/Calcium), Tiludronate (Skelid), and Zoledronic acid (Reclast, Zometa)	<p><u>Update on FDA Safety Review of Bisphosphonates (posted 11/12/2008)</u> The FDA updated their review of safety data concerning the potential increased risk of atrial fibrillation in patients treated with a bisphosphonate drug. After review of all studies, the FDA found no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation observed. Healthcare providers are recommended to continue their prescribing patterns for bisphosphonates and patients should not stop taking their bisphosphonates as well.</p>
Spiriva Handihaler (tiotropium bromide)	<p><u>Preliminary results Show No Increase Risk of Stroke</u> FDA reviewed preliminary data from UPLIFT (Understanding the Potential Long-term Impacts on Function with Tiotropium), a large, 4-year, placebo controlled clinical trial with Spiriva Handihaler in approximately 6000 patients with COPD. Boehringer Ingelheim, manufacturer of Spiriva Handihaler, reported to the FDA that there was no increased risk of stroke with tiotropium bromide compared to placebo in their preliminary results.</p>

NCEP ATP III CHOLESTEROL CLINICAL GUIDELINE UPDATES

The National Cholesterol Education Program (NCEP) recently updated the 2001 Adult Treatment Panel (ATP) III guideline based on clinical evidence derived from five major clinical trials for the management of lipid disorders. The new recommendations are endorsed by The National Heart, Lung, and Blood Institute, the American College of Cardiology, and the American Heart Association and call for a more aggressive management of hyperlipidemia especially in patients at high risk for CHD.

Envision Rx recognizes the importance of the new clinical guidelines updates and includes the following study highlights:

- Aggressive LDL lowering in high-risk patients—drug therapy should be initiated in patients with LDL cholesterol levels between 100 and 129 mg/dL
- The intensity of LDL-lowering therapy should be sufficient to achieve at least a 30% to 40% reduction in LDL cholesterol levels
- Additional benefits have been seen in very high-risk patients with LDL cholesterol goal achieved less than 70mg/dL. The guideline recommends the optional use of drug therapy to bring LDL cholesterol down to less than 70 mg/dL in this subset of patients. Very high-risk patients are those with multiple and severe risk factors, such as metabolic syndrome, diabetes, and smoking.
- Statins are recommended as first-line and should first be maximized before adding on a second agent such as a bile acid sequestrant or nicotinic acid.
- For patients with high triglycerides and low HDL-cholesterol levels, fibrates and nicotinic acid are recommended as adjuncts to statins.
- All CHD-risk equivalent patients should be introduced to lifestyle modifications or TLC (reduced intake of saturated fats, increase in physical activity for at least 30 minutes of cardio workout most days of the week, weight control with BMI goal <30, reduce excessive alcohol use, smoking cessation) in addition to drug therapy.

Risk Category	LDL Goal (mg/dL)	When to initiate therapeutic lifestyle changes	When to consider drug therapy
CHD or CHD Risk Equivalent (10 year risk > 20%)	< 100, (< 70)*	≥ 100	≥ 100 mg/dL
Multiple (2+) Risk Factors, 10 year CHD risk ≤ 20%	< 130	≥ 130	10-year CHD risk 10-20% ≥ 130mg/dL 10 year CHD risk < 10% ≥ 160mg/dL
0 – 1 Risk Factor	< 160	≥ 160	≥ 190 mg/dL

Steps to Initiate Drug Therapy:

- Initiate LDL-C lowering therapy: with a statin, bile acid sequestrant, or nicotinic acid.

At 6 week evaluation:

- If goal is not achieved consider intensifying LDL-C lowering therapy: higher dose of statin, or add bile acid sequestrant, or nicotinic acid. Reevaluate at 12 weeks.

At 12 week evaluation:

- If goal is not achieved consider intensifying LDL-C lowering therapy further or refer to lipid specialist.
- If goal is achieved, treat other lipid risk factors.
- Continue to monitor fasting lipoprotein profile every 4 to 6 months, patient adherence and tolerance to therapy.

A comprehensive summary of the NCEP Cholesterol Treatment Guideline, is available at ("insert hyperlink here")

NEW GENERIC DRUG APPROVALS

Brand-name drug	Generic-name drug	Dosage Forms/Strengths	Therapeutic Drug Class	Approval Date	Manufacturer
PRILOSEC	Omeprazole	40mg capsule, delayed release pellets	Proton Pump Inhibitors	1/21/09	SANDOZ PHARMACEUTICAL INC.
CLOBEX TOPICAL LOTION	Clobetasol propionate	Topical lotion, 0.05%	Topical Corticosteroid	12/4/08	ACTAVIS MID ATLANTIC LLC
DIAMOX ER	Acetazolamide	500mg extended-release capsule	Ophthalmic Agent, Antiglaucoma; Diuretic, Carbonic Anhydrase Inhibitor	12/10/08	ZYDUS PHARMACEUTICALS INC.
KEPPRA	Levetiracetam	250mg, 500mg, 750mg tablets	Anticonvulsant	11/3/08	MYLAN PHARMACEUTICALS INC.
AUGMENTIN 250 Susp	Amoxicillin and clavulanate potassium	250 mg/62.5 mg (base)/5 mL oral suspension	Penicillin Antibiotic	11/25/08	MORTON GROVE PHARMACEUTICALS INC.

Source: FDA, Office of Generic Drugs, First Time Generics available: <http://www.fda.gov/cder/ogd/approvals/default.htm>

WE'RE ON THE WEB!

Free access to health resources:

- [Latest News: Press releases, newsletters, fast facts](#)
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- [Health & Drug Information](#)
- [Adverse Reaction Reporting](#)
- [Professional Comment Form](#)
- [Customer Service Information](#)

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REFERENCES

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- <http://www.medicalnewstoday.com>

Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Updated 2004.

Antihypertensives and Lipid Lowering Treatment to Prevent Heart Attack and seizure (ALLHAT). Viewed website www.medscape.com/viewarticle/479879

