

AU InforMed

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Key Inforbits

- Two new drugs and a NEW OTC
- Many MedWatches of importance
- Rx's surpass heroin and cocaine
- Vocabulary – Lactivists and Social Engineering
- Free lunch! Myth or reality?
- Sun exposure worldwide, according to WHO

NEW DRUGS, and other related stuff ...

Plan B ... is back ... The FDA announced July 31, 2006 that it is proceeding to work with DuraMed (subsidiary of Barr Pharmaceuticals) to resolve remaining policy issues associated with making **Plan B** (emergency contraceptive or “morning after pill” containing a high dose of oral contraceptive hormones) **over-the-counter**, for women ≥ 18 years old. More information is available at: <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01421.html>
FDA announces framework for moving emergency contraception medication to over-the-counter status. *FDA Statement*. 2006 Jul 31.

New Drug ... idursulfase (Elaprase™ by Shire Human Genetic Therapies, Inc) was approved by the FDA on July 24, 2006. It is the first product for Hunter Syndrome (Mucopolysaccharidosis II, [MPS II]) and also is a designated orphan product. Hunter Syndrome is a rare (approximately 1 in 65,000 to 132,000 births), inherited disease in which the body is defective in producing an enzyme needed to breakdown complex sugars.
FDA approves first treatment for Hunter Syndrome. *FDA News*. 2006 Jul 24; P06-104.
<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01418.html>

New Drug ... The FDA approved **Anthelios SX™** July 24, 2006. It is a combination of three active ingredients: ecamsule (new molecular entity), avobenzone and octocrylene, from L'Oreal to be sold over-the-counter (OTC) for the prevention of sunburn and for protection against ultraviolet B (UVB) and ultraviolet A (UVA) rays. It has a sun protection factor (SPF) of 15. The product will be distributed by LaRoche-Posay.
FDA approves a new over-the-counter sunscreen product. *FDA News*. 2006; P06-103
<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01417.html>

New Generic ... The FDA approved several first **generic versions of meloxicam** (Mobic® by Boehringer Ingelheim) on July 19, 2006, indicated for the treatment of osteoarthritis. The approval of meloxicam was the result of a “cluster” review approach, one of the process improvements the FDA has instituted to facilitate the review of generic drug applications. The FDA’s Office of Generic Drugs (OGD) has begun to review groups of applications submitted at the end of 5 year new chemical entity (NCE) exclusivity in “clusters” to increase efficiency and decrease review time. At the expiration of 5 year exclusivity, FDA often receives multiple applications from different sponsors, submitted on the same day. In the case of meloxicam, OGD received over 20 abbreviated new drug applications (ANDAs) and FDA’s review team effort

resulted in the approval of 13 generic applications for this product in a little over 9 months of review time, resulting in the first time any generic version of this product is available. FDA approves first generic meloxicam. *FDA News*. 2006 Jul 19; P06-100. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01412.html>

MedWatch ... The FDA announced important information from two recent studies to consider when making treatment decisions in **pregnant women who take antidepressants**. The studies included pregnant women who were treated with selective serotonin reuptake inhibitors (SSRIs), or in a few cases, other antidepressant medications. In one study, women who stopped their medicine were five times more likely to have a relapse of depression during their pregnancy than were women who continued to take their antidepressant medicine while pregnant. A second study suggests there may be additional, rare, risks of taking SSRI medications during pregnancy. Persistent Pulmonary Hypertension (PPHN) was six times more common in babies whose mothers took an SSRI antidepressant after the 20th week of pregnancy compared to babies whose mothers did not take an antidepressant. Additionally, the labeling for paroxetine (Paxil) was recently changed to add information about findings in an epidemiologic study that suggests that exposure to the drug in the first trimester of pregnancy may be associated with an increased risk of cardiac birth defects.

Women who are pregnant or thinking about becoming pregnant should not stop any antidepressant medication without first consulting their physician. FDA has asked the sponsors of all SSRIs to change prescribing information to describe the potential risk for PPHN. Read the MedWatch 2006 Safety summary, including links to FDA Public Health Advisory at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#SSRIpreg>

MedWatch ... The FDA announced new safety information regarding taking medications used to treat migraine headaches (triptans) together with certain types of antidepressant and mood disorder medications (selective serotonin reuptake inhibitors (SSRIs) and selective serotonin/norepinephrine reuptake inhibitors (SNRIs)). A life-threatening condition called **serotonin syndrome** may occur when triptans are used together with a SSRI or a SNRI. Each of the above medications (triptans, SSRIs, and SNRIs), cause an increase in serotonin levels. Symptoms of serotonin syndrome may include restlessness, hallucinations, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting, and diarrhea.

Patients taking a triptan along with an SSRI or SNRI should talk to their doctor before stopping their medication and should immediately seek medical attention if they experience any of the above symptoms. The FDA requested that all affected manufacturers update their prescribing information to warn of the possibility of serotonin syndrome with these medications together. Read the MedWatch 2006 Safety summary, including links to FDA Public Health Advisory at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Triptans>

MedWatch ... Berlex, Inc. and the FDA announced a **voluntary nationwide recall** of a single lot (No. 41500A, Exp. 1/2007) of **Ultravist (iopromide)** Injection 370 mgI/mL, 125 ml, an intravenous X-ray contrast agent, due to the presence of particulate matter in conjunction with crystallization. Problems may include thrombosis of blood vessels, thromboembolism and injury or infarction of end organs such as heart, kidney, and brain. Hospitals, imaging centers and other healthcare facilities should not use any of the affected lot number (41500A) and should immediately quarantine any product for return.

Read the MedWatch 2006 Safety summary, including a link to the Berlex, Inc. Press Release at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Ultravist>

MedWatch ... FDA notified healthcare professionals and consumers not to use an injectable product called **Bismacine, a.k.a. Chromacine**. Bismacine is not a pharmaceutical and has not been approved to treat any condition however, it is being prescribed or administered by doctors of "alternative health" to treat Lyme disease. This product contains high amounts of bismuth, a heavy metal that is used in some medications taken by mouth to treat *Helicobacter pylori*, a bacteria that can cause stomach ulcers. Bismacine is not approved in any form for use by injection. The FDA is investigating one report of death and several reports of injury. Individuals who believe they have suffered adverse events from receiving Bismacine should seek medical attention. Effects of bismuth poisoning may include cardio-vascular collapse and kidney failure. Read the MedWatch 2006 Safety summary, including links to the FDA Press Release at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Bismacine>

MedWatch ... FDA warned consumers not to purchase or to use **high-strength hydrogen peroxide** products, including a product marketed as "35 Percent Food Grade Hydrogen Peroxide," for medicinal purposes because they can cause serious harm or death when ingested. FDA has never approved it to be taken internally and considers it dangerous, even if handled according to manufacturer's directions. High-strength hydrogen peroxide (≥ 10 times stronger than the solution used in OTC drugs to disinfect minor cuts) is highly corrosive. Ingesting hydrogen peroxide can cause gastrointestinal irritation or ulceration. Intravenous (IV) administration of hydrogen peroxide can cause inflammation of the blood vessel at the injection site, gas embolisms (bubbles in blood vessels), and potentially life-threatening allergic reactions. Read complete MedWatch 2006 Safety summary, including a link to the FDA news release, at: <http://www.fda.gov/medwatch/safety/2006/safety06.htm#Peroxide>

FROM THE MEDICAL LITERATURE ...

Rx opioids most deadly ... Tracking data for deaths due to opioids has shown a dramatic increase for the period of 1999 to 2002. Most significant seems to be the contribution of prescription opioids to death rates (increased 129%). For deaths attributable to a single drug (opioids, cocaine or heroin) more people have died from the opioids than from the cocaine and heroin combined. This apparently mirrors the trend for increased numbers of prescriptions for these agents.



Paulozzi LJ, Budnitz DS, Yongli X. Increasing deaths from opioid analgesics in the United States. *Pharmacoepidemiol Drug Safety*. 2006; online, DOI: 10.1002/pds.1276.

<http://www3.interscience.wiley.com/cgi-bin/abstract/112728907/ABSTRACT?CRETRY=1&SRETRY=0>

Reviews of Note ...

- Moser M, Setaro JF. Resistant or difficult-to-control hypertension. *N Engl J Med*. 2006 Jul 27;355(4):385-92.
- Nedrow A, Miller J, Walker M, Nygren P, Huffman LH, Nelson HD. Complementary and alternative therapies for the management of menopause-related symptoms: A systematic evidence review. *Arch Intern Med* 2006 Jul 24;166:1453-65.
[Note: 70 articles reviewed on a wide range of therapies, most of which judged to be lacking in rigor or results.]

FROM THE LAY LITERATURE about medicine ...

Vocabulary ... Lactivists ... “Those who advocate for a woman’s right to nurse wherever she needs to.” An age-old controversy recently stimulated by a rather graphic picture on the cover of *Babytalk* magazine. As you might expect, there are strong opinions on all sides.

Associated Press. Lactivists: Where is it OK to breastfeed? *CNN.com* 2006 Jul 27.

<http://www.cnn.com/2006/US/07/27/nursing.cover.ap/index.html>

Is it really a “free lunch?” ... An article examines the cost and impact of the pharmaceutical industry’s new currency, the free lunch (and sometimes breakfast). After the industry was forced to cut back on some extravagant gifts to physicians the “free lunch” has become ubiquitous in many medical practices.

the practice due to feeling is one, and they estimated the year. However, justification



However, some institutions and groups are banning there is undue influence. The University of Michigan “free lunches” there amounted to \$2.5 million per from the physicians comes in the form of the free drug samples that often accompany a visit by the sales rep, and perhaps more important, the office staff has come to expect them; so much so that in some cases, they complain about the fare, eg, pizza twice this week?! Of course, no one feels that this has any influence on prescribing patterns ... except the pharmaceutical industry, who can prove it!

Saul S. Drug makers pay for lunch as they pitch. *New York Times.com*. 2006 Jul 28.

<http://www.nytimes.com/2006/07/28/business/28lunch.html?pagewanted=1&ref=health>



The last “dose” ...



60,000

Premature deaths worldwide, in the year 2000 due to excessive solar UVR exposure.

Lucas R, McMichael T, Smith W, Armstrong B. Solar Ultraviolet Radiation: Global burden of disease from solar ultraviolet radiation. Environmental burden of disease series, No. 13. Geneva: World Health Organization, 2006.

<http://www.who.int/en/>

An electronic bulletin of drug and health-related news highlights, a service of ...

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