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Wednesday, September 7, 2005

Key Inforbits

- New drug and new flu vaccine source
- MedWatches ...
- Hypertension statistics

- Statin STAT!
- Coffee is good!
- Spyware begone

NEW DRUGS, and other related stuff ...

New Drug … mecasermin [rDNA origin] injection (Increlex[™] by Tercica, Inc) was approved by the FDA on August 30, 2005, indicated for the long-term treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. It will be available as a 10mg/mL, 40mg/vial multiple dose injection. For approval history and labeling, go to: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchActi on&ApplNo=021839&SearchType=AddlSearch&SEARCHOPTION=B

New Source ... The FDA recently approved a new flu vaccine, (Fluarix[™] by GlaxoSmithKline). It is a similar formulation as others on the market, but this gives an additional supplier that will hopefully help us avoid the shortage problems of last year. FDA. FDA approves new influenza vaccine for upcoming flu season. FDA News 2005 Aug 31, P05-56. http://www.fda.gov/bbs/topics/news/2005/NEW01227.html

MedWatch ... Medline and the FDA notified healthcare professionals about a nationwide recall of Alcohol-Free Mouthwash and Hygiene Kits containing mouthwash because of potential contamination with *Burkholderia cepacia*. People who have certain health problems such as weakened immune systems or chronic lung diseases, particularly cystic fibrosis (CF), may be more susceptible to infections with *B. cepacia*. The product was distributed to hospitals, medical centers, and long term care facilities nationwide. There is no known distribution through retail sales. The CDC has confirmed hospital illness associated with the use of the affected mouthwash in Texas and Florida. Read the complete MedWatch 2005 Safety summary, including a link to the FDA notice and firm's press release, at:

http://www.fda.gov/medwatch/safety/2005/safety05.htm#medline

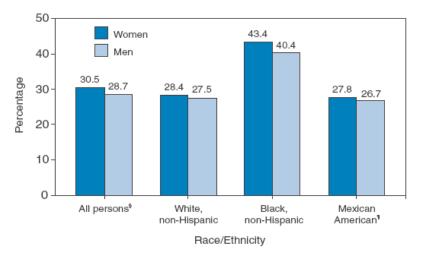
MedWatch ... Genentech and FDA notified healthcare professionals of updated cardiotoxicity information related to the use of Herceptin (trastuzumab), obtained from the National Surgical Adjuvant Breast and Bowel Project (NSABP) study (B-31), a randomized, Phase III trial that was conducted in 2043 women with operable, HER2 overexpressing breast cancer (IHC 3+ or FISH+). Preliminary analysis of safety data from Study NSABP B-31 and the North Central Cancer Treatment Group (NCCTG) study (N9831) revealed a statistically significant increase in the 3-year cumulative incidence of New York Heart Association Class III and IV congestive heart failure and cardiac death observed in patients who received the Herceptin-containing

regimen (4.1%) compared with control (0.8%). Read the completed MedWatch 2005 Safety Summary including the link to the Dear Healthcare Provider Letter at: <u>http://www.fda.gov/medwatch/safety/2005/safety05.htm#Herceptin</u>

FROM THE MEDICAL LITERATURE ...

QuickStats: Percentage* of Persons Aged \geq 20 Years with Hypertension,[†] by Race/Ethnicity --- United States, 1999--2002





* Percentages are age-adjusted to the 2000 U.S. standard population by using five age groups: 20--34, 35--44, 45--54, 55--64, and \geq 65 years.

[†] Defined as either having elevated blood pressure (systolic pressure of \geq 140 mmHg or diastolic pressure of \geq 90 mmHg) or taking antihypertensive medication.

[§] Includes persons of all races/ethnicities (including all Hispanic origins), not just non-Hispanic whites, non-Hispanic blacks, and Mexican Americans.

[¶] Persons in this subpopulation might be of any race.

During 1999--2002, approximately 30% of persons aged \geq 20 years had hypertension. Among those racial/ethnic populations and subpopulations evaluated, the percentage with hypertension was highest among non-Hispanic blacks. Men and women were approximately equally likely to have hypertension. **SOURCES:** National Center for Health Statistics. Health, United States, 2004: with chartbook on trends in the health of Americans. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2004. Available at <u>http://www.cdc.gov/nchs/hus.htm</u>. National Health and Nutrition Examination Survey, 1999--2002. Available at

http://www.cdc.gov/nchs/nhanes.htm.

CDC. QuickStats: Percentage of Persons Aged ≥20 Years with Hypertension, by Race/Ethnicity --- United States, 1999-2002. *MMWR* 2005 Aug26;54(33):826

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5433a4.htm

Clarification of Schedule II prescription guidelines ... The DEA has issued a "clarification" on previous guidelines concerning prescribing of schedule II controlled substances for treatment of pain. One clarification is that multiple prescriptions for a medication, intended to be filled at later times, may not be written, as it constitutes refills, which is not allowed.

Clarification of existing requirements under the Controlled Substances Act for prescribing schedule II controlled substances. *Fed Regist* 2005 Aug 26;70(165):50408-9. http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-16954.pdf

Statin STAT ... In a huge retrospective study (>300,000 patients initially), investigators looked at patients admitted to the hospital with acute myocardial infarction who were on statin therapy or received a statin within 24 hours of the event, vs. those who did not receive a statin or in those where it was discontinued. Their conclusion was "the use of statin therapy within the first 24 hours of hospitalization for AMI is associated with a significantly lower rate of early complications and in-hospital mortality."

Fonarow GC, Wright RS, Spencer FA, et al. Effect of statin use within the first 24 hours of admission for acute myocardial infarction on early morbidity and mortality. *Am J Cardiol* 2005 Sep 1;96(5):611-6. <u>http://www.ajconline.org/article/PIIS0002914905009252/abstract</u> (abstract)

FDA advice on use of potentially contaminated drug products ... Provides advice on what to with prescriptions and other drugs that have been exposed to potentially contaminated water, depending on whether it is an essential vs. nonessential medication, those requiring reconstitution or refrigeration, etc.

http://www.fda.gov/cder/emergency/default.htm

Reviews of Note ...

- Macario A. Systematic literature review of the economics of intravenous patientcontrolled analgesia. *P&T* 2005 Jul;30(7):392-9.
- Strassels SA, McNicol E, Suleman R. Postoperative pain management: A practical review, part 1. *Am J Health-Syst Pharm* 2005 Sep 15;62:1904-16.
- Gillespie EL, White CM, Kardas M, Lingberg M, Coleman CI. The impact of ACE inhibitors or angiotensin II tpe 1 receptor blockers on the development of new-onset type 2 diabetes. *Diabetes Care* 2005 Sep;28(9):2261-66.
- Nutt JG, Wooten GF. Diagnosis and initial management of Parkinson's disease. *N Engl J Med* 2005 Sep 8;353(10):1021-7.
- Di Nisio M, Middeldorp S, Büller HR. Direct thrombin inhibitors. *N Engl J Med* 2005 Sep 8;353(10):1028-40.

FROM THE LAY LITERATURE about medicine ...

Another boost for coffee ... in a paper presented at the American Chemical Society, a chemistry professor showed that if its antioxidants you want, coffee is what you need. His analysis showed that coffee contains many times more antioxidants that various vegetables, fruits, etc. Coffee shouldn't be substituted for these wonderful foods, but it does give another "reason" NOT to give it up.

Study touts coffee's health benefits. *USA Today* 2005 Aug 28. <u>http://www.usatoday.com/news/health/2005-08-28-coffee-antioxidants_x.htm</u>

<u>Update</u> ...

Longyhore DS. Residency programs in primary and ambulatory care pharmacy practice. *Am J Health-Syst Pharm* 2005 Sep 15;62:1868-9.

AUBURN HSOP FACULTY in the literature ...

- Felkey BG, Berger BA, Krueger KP. The pharmacist's role in treatment adherence: Part 5: The impact of pharmacy-specific technology. *US Pharm* 2005 Aug;30(8):36-39.
- Braxton Lloyd K. Perspectives in women's health: hormone replacement therapy. In Supernaw RB, editor. *Perspectives in Pharmaceutical Care*. Weatherford, Oklahoma: Pharmat Inc, 2005.
- Scolaro KL, Stamm PL, Braxton Lloyd K. Devices for ambulatory and home monitoring of blood pressure, lipids, coagulation, and weight management, part 2. *Am J Health-Syst Pharm* 2005 Sep 15;62:1894-1903.

<u>NEW RESOURCES in the DILRC</u> ...

- Tidsdale JE, Miller DA, eds. *Drug-Induced Diseases: Prevention, Detection, and Management*. Bethesda, MD: American Society of Health-System Pharmacists. 2005.
- *Ident-A-Drug Reference: for Tablet and Capsule Identification*. 2005 ed. Stockton, CA: Therapeutic Research Center, 2005.
- Robertson J, Shilkofski N, eds. *The Harriet Lane Handbook*. 17th ed. Philadelphia: Elsevier Saunders, 2005.
- Manasse HR Jr, Thompson KK, eds. *Medication Safety: A Guide for Health Care Facilities*. Bethesda, MD: American Society of Health-System Pharmacists, 2005.
- First MB, Tasman A, eds. *DSM-IV-TR Mental Disorders: Diagnosis, Etiology & Treatment*. London: Wiley, 2004.
- Ireland S. *The Complete Idiot's Guide to the Perfect Resume*. 3rd ed. Indianapolis: Alpha Books, 2003.

TIMELY TOP TECH TIP ...

Spyware got you down? If your computer is running slower these days it could be because you have a bunch of spyware on your hard drive. You need to obtain and run a good antispyware program. Some recommend running several of them initially, to expunge these malicious pieces of software. Some current recommendations in this category are Webroot's *Spy Sweeper*, *Spybot Search and Destroy*, *Ad-Aware* and *CounterSpy*. Your local, neighborhood IT dept. will be glad to advise.

Mossberg WS. Mossberg's Mailbox. Wall Street Journal 2005 Aug 18.

📚 <u>The last "dose"</u> ...

No act of kindness, no matter how small, is ever wasted.

-- Aesop (fl, c. 550 B.C.), from The Lion and the Mouse

An electronic bulletin of drug and health-related news highlights, a service of ... Auburn University, Harrison School of Pharmacy, Drug Information Center
Phone 334-844-4400 • Fax 334-844-8366 • <u>http://www.pharmacy.auburn.edu/dilrc/dilrc.htm</u> Bernie R. Olin, Pharm.D., Director