

AU InforMed

Volume 3 Number 9 (Issue 72)

Thursday, April 7, 2005

NEW DRUGS, and other related stuff ...

Public Health Advisory ... FDA issued a public health warning April 7, 2005 and has asked Pfizer, Inc. to **withdraw Bextra[®] (valdexocib)** from the market because the overall risk versus benefit profile for the drug is unfavorable. FDA has also asked Pfizer to include a boxed warning in the Celebrex[®] (celecoxib) label. Pfizer has agreed to suspend sales and marketing of Bextra[®] in the U.S., pending further discussions. FDA is also asking manufacturers of all other prescription NSAIDs to revise their labels to include the same boxed warning highlighting the potential for increased risk of cardiovascular (CV) events and gastrointestinal (GI) bleeding associated with their use; similar warnings are also being requested for OTC NSAIDs. For much more information go to the FDA web site:

<http://www.fda.gov/bbs/topics/news/2005/NEW01171.html>

New Drug ... **Bromfenac** (Xibrom[™] ophthalmic solution by ISTA Pharmaceuticals) 0.09% for the treatment of ocular inflammation following cataract surgery was approved by the FDA on March 28, 2005. ISTA expects to launch Xibrom[™], a topical, twice-daily, non-steroidal anti-inflammatory solution (NSAID), during the second quarter of 2005. For more information and product labeling, go to:

<http://www.istavision.com/>

New Drug ... The FDA announced March 30, 2005 the approval of **entecavir** tablets and oral solution (Baraclude[™] by Bristol-Myers Squibb) for the treatment of chronic hepatitis B in adults. According to the Centers for Disease Control and Prevention (CDC), approximately 1.25 million Americans are chronically infected with the HBV virus. Entecavir slows the progression of chronic hepatitis B by interfering with viral reproduction. FDA based its approval of Baraclude on the results of three studies in which entecavir was compared to another anti-viral drug, lamivudine. Package labeling states that patients who discontinue entecavir should be monitored at repeated intervals over a period of time for liver function.

FDA approves new treatment for chronic hepatitis B. *FDA Talk Paper* 2005 Mar 30; T05-11.

<http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01348.html> (FDA Talk Paper)

<http://www.baraclude.com/> (Complete prescribing information)

New Formulation ... the FDA announced April 1, 2005 that an IV form of Nexium (esomeprazole magnesium by AstraZeneca) has been approved. It is now approved as an IV infusion or injection for the short-term treatment (up to 10 days) of gastroesophageal reflux disease (GERD) patients, with a history of erosive esophagitis, unable to take the capsules.

<http://www.astrazeneca.com/pressrelease/4975.aspx>

MedWatch ... Harmony Brands of Oak Park, Michigan, is voluntarily recalling its **B-Sure Brand One-Step Home Pregnancy Test** because its safety and efficacy can no longer be

assured. Consumers who have the product in their possession should not use it and should return the product to the point of purchase for a refund. Women who have used the test may wish to contact their health care provider to verify the test results. There have been no reports of failures of the product, and there have been no reports of injury or illness associated with their use. Read the complete MedWatch 2005 Safety summary, including a link to the firm's press release at: <http://www.fda.gov/medwatch/SAFETY/2005/safety05.htm#BSure>

MedWatch ... Ortho-McNeil Neurologics modified the prescribing information for **Reminyl[®]** (**galantamine HBr**), approved for mild to moderate Alzheimer's Disease. The changes provide new safety information from two randomized, placebo-controlled trials of 2 years duration in subjects with mild cognitive impairment (MCI). A total of 13 subjects on Reminyl[®] (n=1026) and 1 subject on placebo (n=1022) died. The deaths were due to various causes which could be expected in an elderly population. About half of the Reminyl[®] deaths appeared to result from vascular causes (myocardial infarction, stroke), and sudden death. Read the complete MedWatch 2005 Safety summary, including a link to the Dear Healthcare Professional letter at: www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Reminyl

Banned ... The FDA announced March 31, 2005 that albuterol metered-dose inhalers (MDIs) using **chlorofluorocarbon (CFC)** propellants must no longer be produced, marketed or sold in the United States after December 31, 2008. In a final rule published in the *Federal Register*, HHS said sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008 to allow the phasing out of similar less environmentally friendly versions. Manufacturers are cooperating; HHS is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDIs for patients for whom price could be a significant barrier.

FDA publishes final rule on chlorofluorocarbons in metered dose inhalers. *FDA Talk Paper* 2005 Mar 31; T05-12. <http://www.fda.gov/bbs/topics/ANSWERS/2005/ANS01349.html>

FROM THE MEDICAL LITERATURE ...



QuickStats ... from the CDC, comes from 2002 data on use of **complementary/alternative** medicine in the U.S. According to the National Center for Health Statistics, nearly 70% of women and 54% of men have used Comp/Alt therapy of all types in the preceding 12 months. For natural products the percentages are 21% and 17%, respectively.

QuickStats: Percentage of adults aged ≥ 18 years who used complementary and alternative medicine (CAM) during the preceding 12 months, by sex – United States, 2002. *MMWR* Mar 25;54(11):283.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5411a6.htm>



Cancer prevention – up to you ... According to a 60-page report released March 31, 2005 by the American Cancer Society, lifestyle changes and better use of screening tests can prevent at least 50% of all cancer deaths. Such things as quitting smoking, maintaining a healthy body weight, exercising and eating a balanced diet play a large role in cutting the risk for developing several cancers. Probably no big surprise, but eliminating smoking would have the single biggest impact; estimates are that tobacco will contribute to 168,140 cancer deaths this year. Obesity, poor nutrition, physical inactivity and other lifestyle factors are attributed to another 190,090 cancer deaths. About 570,280 people are estimated to die of cancer in the U.S. this year. For the full report, go to:

American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2005*. Atlanta: American Cancer Society, 2005.

http://www.cancer.org/docroot/STT/content/STT_1x_Cancer_Prevention_and_Early_Detection_Facts_and_Figures_2005.asp

Reviews of Note ...

- Wadden TA, Stunkard AJ, Berkowitz RI, eds. Obesity: A guide for mental health professionals. *Psychiatric Clin N Am* 2005 Mar;28(1):1-299. (14 articles)
- Singh AK, ed. Chronic kidney disease. *Med Clin N Am* 2005 May;89(3):419-720.
- Silberstein SD, Ben-Menachem E, Shank RP, Wiegand F. Topiramate monotherapy in epilepsy and migraine prevention. *Clin Ther* 2005 Feb;27(2):154-65.
- Greenblatt D. Treatment of postmenopausal osteoporosis. *Pharmacotherapy* 2005 Apr;25(4):574-84.
- Abramowicz M, ed. Drugs for non-HIV viral infections. *Treatment Guidelines* 2005 Apr;3(32):23-32.
- James WD. Acne. *N Engl J Med* 2005 Apr 7;352(14):1463-72.

FROM THE LAY LITERATURE about medicine ...



Noncompliance rampant ... In a survey of over 2500 adults, conducted by Harris Interactive for the Wall Street Journal, it was found that one-third of those surveyed described themselves as very noncompliant with prescription drugs. The most common reasons were “I forgot,” concerns about the drug itself, or they felt the drug was unnecessary. Bright B. Many U.S. adults fail to take prescription drugs as prescribed: WSJ Online/Harris Interactive Health-care Poll. *Wall Street Journal online* 2005 Mar 29.

AUBURN HSOP FACULTY in the literature ...

- Berger BA, Felkey BG, Krueger KP. The pharmacist’s role in treatment adherence, Part 3: Applying motivational interviewing principles. *US Pharm* 2005 Mar;30(3):38-47.
- Riley TN, DeRuijter J. New drug review. *US Pharm* 2005 Mar;30(3):95-106.



The last “dose” ...

“Half the modern drugs could well be thrown out the window, except that the birds might eat them.”

--Martin H. Fischer [1879-1962]

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 • <http://www.pharmacy.auburn.edu/dilrc/dilrc.htm>

Bernie R. Olin, Pharm.D., Director