

CENTENE PHARMACY & THERAPEUTICS COMMITTEE REVIEW Q2 2011 FDA UPDATE

March 24. The FDA cleared Zostavax (zoster vaccine live) for use above the age of 50. The FDA it widened the age group based upon clinical trial data showing it reduced the risk of outbreaks by 70 percent in that age range.

March 16. Embeda was removed from the market as a result of ongoing stability problems. The drug contains pellets of morphine that surround naltrexone, a chemical which blocks opiate effects if the product is crushed or chewed, thereby deterring misuse or abuse. The naltrexone component was shown to have degraded to unacceptable levels in samples of Embeda that were tested.

March 10. The FDA approved Benlysta (belimumab) to treat patients with active, autoantibody-positive lupus (systemic lupus erythematosus) who are receiving standard therapy, including corticosteroids, antimalarials, immunosuppressives, and nonsteroidal anti-inflammatory drugs. Benlysta is delivered by intravenous infusion and is the first inhibitor designed to target B-lymphocyte stimulator (BLyS) protein, which may reduce the number of abnormal B cells thought to be a problem in lupus.

March 09. The FDA approved a generic version of Taxotere.

March 01. The FDA has approved Daliresp (roflumilast) as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

February 28. The FDA approved Intuniv (guanfacine) extended-release tablets for use as an adjunctive therapy to stimulants for the treatment of attention deficit hyperactivity disorder in children and adolescents. Intuniv is the first once-daily nonstimulant to be approved for use alone or in combination with stimulants for treatment of ADHD.

February 25. The FDA approved Edarbi tablets (azilsartan medoxomil) to treat high blood pressure (hypertension) in adults. Edarbi is an angiotensin II receptor blocker (ARB)

February 25. The FDA approved a generic version of Xyzal (levocetirizine dihydrochloride) a treatment for allergic rhinitis.

February 18. The FDA approved Corifact, the first product intended to prevent bleeding in people with the rare genetic defect congenital Factor XIII deficiency.

February 07. The FDA approved a generic of Hycamtin (topotecan) injection for treating small-cell lung cancer sensitive disease after first-line chemotherapy has failed.

February 07. The FDA notified healthcare professionals and patients that information on the cardiovascular risks (including heart attack) of rosiglitazone has been added to the physician labeling and patient Medication Guide. In addition to describing the cardiovascular risks, the drug labels have been revised to state that rosiglitazone and rosiglitazone-containing medicines should only be used: in patients already being treated with these medicines, in patients whose blood sugar cannot be controlled with other anti-diabetic medicines and who, after consulting with their healthcare professional, do not wish to use pioglitazone-containing medicines

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February 07. The FDA approved Makena (hydroxyprogesterone caproate), the first drug to help prevent premature birth in women who have had at least one previous preterm delivery. Centene has already been supplying the drug to providers' offices when meeting criteria, and as supplied by compounding pharmacies. The drug is not intended for use in women with a multiple pregnancy, such as a twin pregnancy, or other risk factors for preterm birth.

February 04. The FDA approved the vaccine Gardasil for the prevention of anal cancer and associated precancerous lesions due to human papillomavirus (HPV) types 6, 11, 16, and 18 in people ages 9 through 26 years

February 03. The FDA approved extended-release galantamine hydrobromide in 8 mg, 16 mg and 24 mg capsules. The product is a generic version of Razadyne ER.

January 26. The FDA has approved Allegra medications for over-the-counter use in adults and children age 2 and older. The products to be made available include Allegra 24-Hour and 12-Hour Tablets for adults and children 12 and older; Children's Allegra 12-Hour Tablets for age 6 and older, and Liquid for use in children age 2 and older; Children's Allegra 12-Hour Orally Disintegrating Tablets for use in children age 6 and older; and Allegra-D 24-Hour and 12-Hour Allergy and Congestion Extended Release Tablets, with a decongestant, for use in children age 12 and older.

January 21. The FDA approved Viibryd tablets (vilazodone hydrochloride) to treat major depressive disorder in adults.

January 18. The FDA approved Natroba (spinosad) Topical Suspension 0.9% for the treatment of head lice infestation in patients ages 4 years and older.

January 14. The FDA is alerting healthcare professionals and patients about cases of rare, but severe liver injury, including two cases of acute liver failure leading to liver transplant in patients treated with the heart medication dronedarone (Multaq). Dronedarone is a drug used to treat abnormal heart rhythm in patients who have had an abnormal heart rhythm (atrial fibrillation or atrial flutter) during the past 6 months.

January 13. The FDA is asking manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule. The FDA also is requiring manufacturers to update labels of all prescription combination acetaminophen products to warn of the potential risk for severe liver injury.

January 07. The FDA approved Abstral (fentanyl) transmucosal tablets to manage breakthrough pain for adults with cancer.

December 30. The FDA has approved testosterone gel (Fortesta Gel) for the treatment of hypogonadism.