

PHARMACY & THERAPEUTICS COMMITTEE REVIEW
Q3 2011 FDA UPDATE

June 22. The FDA approved nitroglycerin ointment 0.4% (*Rectiv*, ProStrakan Group) for the treatment of moderate to severe pain associated with chronic anal fissures,

June 20. The FDA approved the first generic versions of Levaquin (levofloxacin).

June 20. The FDA has approved a new formulation of oxycodone hydrochloride (HCl), USP tablets (Oxecta) CII. The new formulation is indicated for the management of acute and chronic moderate to severe pain when the use of an opioid analgesic is appropriate. The product is an immediate-release oxycodone medication that applies technology designed to discourage common methods of tampering associated with opioid abuse and misuse. This technology, known as Aversion Technology, uses commonly available pharmaceutical ingredients that, for example, cause the active ingredient to gel to prevent injection or to irritate nasal passages to discourage inhalation.

June 15. The FDA approved Nulojix (belatacept) to prevent acute rejection in adult patients who have had a kidney transplant. The drug is approved for use with other immunosuppressants (medications that suppress the immune system) -- specifically basiliximab, mycophenolate mofetil, and corticosteroids

June 10. The FDA approved Potiga (ezogabine) for use as an add-on medication to treat partial seizures in adults.

June 06. Twelve generic-drug makers received FDA approval to market their versions of Novartis' breast cancer treatment Femara (letrozole).

May 31. The FDA has approved a generic version of Combivir (zidovudine and lamivudine).

May 27. The FDA approved a sterile, injectable gel called Solesta to treat fecal incontinence in patients after other remedies have failed. Solesta, a bulking agent, is injected just beneath the anus lining with the aim of expanding area tissue. When achieved, that expansion narrows the opening of the anus, which may help patients better control their bowel movements,

May 27. The U.S. Food and Drug Administration today approved Dificid (fidaxomicin) tablets for the treatment of Clostridium difficile-associated diarrhea (CDAD).

May 23. The FDA has approved telaprevir (Incivek) for the treatment of hepatitis C virus (HCV) infection. Telaprevir is approved for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in patients aged 18 years and older with compensated liver disease, including cirrhosis, who are treatment-naive or who have been previously treated with interferon-based treatment.

May 20. The FDA has approved once-daily rilpivirine (Edurant) for treatment of HIV infection. Rilpivirine is a nonnucleoside reverse transcriptase inhibitor (NNRTI) that may be taken once daily in combination with other antiretroviral drugs for HIV-infected, treatment-naive patients.

May 20. The FDA has approved sunitinib malate (Sutent) for the treatment of pancreatic neuroendocrine tumors (NETs), making it the first antivasculature endothelial growth factor receptor (anti-VEGF) therapy for this disease.

May 16. Mylan announced the launch of the first generic version of Xibrom[®] (bromfenac ophthalmic solution, 0.09%). Xibrom is a topical non-steroidal anti-inflammatory drug (NSAID) used for the treatment of postoperative inflammation in patients who have undergone cataract extraction. The eye drops are administered twice daily for two weeks following surgery.

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May 13. The FDA approved Victrelis™ (boceprevir) for treatment-naïve and treatment-experienced patients with genotype 1 chronic hepatitis C virus (HCV) infection. Victrelis is the first oral hepatitis C protease inhibitor to be approved by FDA. It works by inhibiting the enzyme that allows the hepatitis C virus to replicate.

May 10. Sanofi Pasteur received FDA approval of flu vaccine Fluzone Intradermal, which comes with a short and fine needle. The vaccine is intended for people ages 18 to 64. Availability is expected for the 2011-12 flu season.

May 06. The FDA cleared the first test for Staphylococcus aureus (S.aureus) infections that is able to quickly identify whether the bacteria are methicillin resistant (MRSA) or methicillin susceptible (MSSA). The KeyPath MRSA/MSSA Blood Culture Test was approved based on a clinical study of 1,116 blood samples evaluated at four major U.S. hospital centers. Within the organisms determined to be S.aureus, the MRSA determination was 98.9% accurate (178/180) and the MSSA determination was 99.4% accurate (153/154).

May 06. The FDA approved Afinitor (everolimus) to treat patients with progressive neuroendocrine tumors located in the pancreas (PNET) that cannot be removed by surgery or that have spread to other parts of the body (metastatic). Afinitor was previously approved to treat patients with advanced renal cell carcinoma after failure with Sutent (sunitinib) or Nexavar (sorafenib); and for subependymal giant cell astrocytoma associated with tuberous sclerosis (a disease that causes tumors in various parts of the body), who cannot be treated by surgery.

May 02. A generic version of Concerta was made available in limited supply. There should be no expectations of major cost savings based on likely cross-licensing agreements for the proprietary OROS drug release technology.

May 02. The FDA approved linagliptin (Tradjenta, Eli Lilly Co and Boehringer Ingelheim Pharmaceuticals) for improving blood glucose control in adults with type 2 diabetes, either as monotherapy or in combination with other therapies. Linagliptin, will be made available in tablet form. It boosts the level of hormones that stimulate the release of insulin after a meal by blocking an enzyme called dipeptidyl peptidase-4.

April 28. The FDA approved Zytiga (abiraterone acetate) in combination with prednisone (a steroid) to treat patients with late-stage (metastatic) castration-resistant prostate cancer who have received prior docetaxel (chemotherapy).

April 25. The FDA approved Duexis®, a fixed dose combination of ibuprofen (800mg) and famotidine (26.6mg).

April 25. Following a settlement agreement, Mylan launched its generic to Femara® (letrozole) 2.5mg tablets. The FDA is expected to approve additional generics after the drug's patent expires on June 3, 2011. Currently, there are eight manufacturers with generics to Femara "tentatively approved" by the FDA.

April 24. The FDA approved Menactra for protecting children as young as 9 months against meningococcal disease caused by Neisseria meningitides. Menactra is already used in people ages 2 to 55.

April 19. The FDA approved Rituxan (rituximab), in combination with glucocorticoids (steroids), to treat patients with Wegener's granulomatosis (WG) and microscopic polyangiitis (MPA), two rare disorders that cause blood vessel inflammation (vasculitis)

April 15. The FDA approved Actemra, (tocilizumab), to treat patients age 2 and older with active systemic juvenile idiopathic arthritis. Actemra is given alone or with methotrexate. The drug originally was approved early last year for adults who respond poorly to tumor necrosis factor antagonists.

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April 15. The FDA is requiring drugmakers to conduct post-marketing studies to evaluate the safety of long-acting beta-agonists when combined with inhaled corticosteroids for patients with asthma. The tests are expected to begin this year. Four trials will enroll 46,800 patients age 12 and older. The agency also asked GlaxoSmithKline to separately evaluate its Advair Diskus in 6,200 children ages 4 to 11.

April 15. The FDA has approved Horizant extended-release tablets (gabapentin enacarbil), a once-daily treatment for moderate-to-severe restless legs syndrome (RLS), also known as Ekbom disease. It is the first medication in its class to be approved for this condition.

April 15. The FDA issued drug safety communications about a serious adverse effect associated with the use of over-the-counter (OTC) benzocaine gels, sprays, and liquids applied to the throat and gums to reduce pain. In its communication to healthcare professionals, FDA is warning the public that the use of benzocaine is associated with methemoglobinemia. In the most severe cases, methemoglobinemia can result in death. The cases occurred mainly in children aged 2 years or younger who were treated with benzocaine gel for teething. Benzocaine gels and liquids are sold OTC under different brand names such as Anbesol, Hurracaine, Orajel, Baby Orajel, Orabase, and store brands.

April 11. The FDA continues to receive reports of hepatosplenic T-cell lymphoma (HSTCL) in adolescents and young adults treated with tumor necrosis factor (TNF) blockers, azathioprine, and/or mercaptopurine. HSTCL has been reported in patients taking immunosuppressive drugs for Crohn's disease, ulcerative colitis, psoriasis, and rheumatoid arthritis.

April 11. The FDA expanded approval of Invega, an extended-release drug for schizophrenia, to include use in 12- to 17-year-olds. Invega was initially approved in 2006 for adults.

April 08. The FDA has approved Xpert C difficile/Epi, a test for detecting an epidemic strain of Clostridium difficile, 027/NAP1/BI. The test, which can generate results in fewer than 45 minutes, can spot the toxin B gene linked to the bacterial infection in stool samples.

April 05. The FDA approved vandetanib to treat adult patients with late-stage (metastatic) medullary thyroid cancer who are ineligible for surgery and who have disease that is growing or causing symptoms.

April 04. The FDA has approved an extended-release version of Viramune (HIV treatment). The new formulation can be taken once a day instead of twice a day.

April 04. The FDA approved Mylan's generic for Xalatan, latanoprost ophthalmic solution.

April 01. The FDA has approved has approved Nulecit (sodium ferric gluconate complex in sucrose), an injectable and generic version of Ferrlecit.

April 01. The FDA notified healthcare professionals of serious health risks that have been reported in premature babies receiving lopinavir/ritonavir (Kaletra, Abbott) oral solution.

April 01. Prescription proton pump inhibitors (PPIs) may cause hypomagnesemia if taken for prolonged periods of time (in most cases longer than 1 year). The FDA recommends that healthcare professionals consider obtaining serum magnesium levels prior to the initiation of PPI therapy for those patients who they anticipate will be on a long course of therapy, as well as from those taking digoxin, diuretics, or drugs that may cause hypomagnesemia.

ABSOLUTE TOTAL CARE



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March 25. Dr. Reddy's Laboratories has launched Levocetirizine tablets (5mg), a bioequivalent generic version of Xyzal® tablets in the US market. The FDA approved Dr. Reddy's ANDA for Levocetirizine tablets on February 24, 2011.

March 25. The FDA approved Yervoy™ (ipilimumab) 3 mg/kg for the treatment of patients with unresectable (inoperable) or metastatic melanoma. Yervoy™ is the first and only therapy for unresectable or metastatic melanoma to demonstrate a significant improvement in overall survival.

March 25. The FDA approved the use of Zostavax, a live attenuated virus vaccine, for the prevention of shingles in individuals 50 to 59 years of age. Zostavax is already approved for use in individuals 60 years of age and older.

March 22. The FDA approved Adenovirus Type 4 and Type 7 Vaccine, Live, Oral which is indicated for active immunization to prevent febrile acute respiratory disease caused by Adenovirus Type 4 and Type 7. Oral is approved for use in military populations 17 to 50 years of age.