SXC Health Solutions, Inc.

RxHighlights™

Vol. 5, Issue 6, 2012 **May 2012**

a monthly summary of pharmacy news and events

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new products

TRADE NAME (generic name) Company(ies)	Therapeutic Category	Strength(s) & Dosage Form(s)	Indication(s)	Dosing	Similar Products
ELELYSO (taliglucerase alfa) Protalix; Pfizer	Hematopoietic Agents	200 unit single use vials containing lyophilized powder for reconstitution with diluent	Long-Term Enzyme Replacement Therapy for Adults with a Confirmed Diagnosis of Type 1 Gaucher Disease	60 units/kg once every 2 weeks as a 60 to 120 minute intravenous infusion	CEREZYME VPRIV

new generics

Generic Name	Company(ies)	Therapeutic Category	Strength(s) & Dosage Form(s)	Trade Name Equivalent	Comments/Availability
vardenafil hydrochloride	Teva	Impotence Agents	2.5 mg, 5 mg, 10 mg, & 20 mg tablets	LEVITRA	A-rated generic. Bayer and Teva are in patent litigation. Estimated availability of a generic launch is 2018.
carbidopa / levodopa / entacapone	Sun	Antiparkinson Agents	25 mg/100 mg/200 mg & 37.5 mg/150 mg/200 mg tablets	STALEVO	A-rated generic.
clopidogrel bisulfate	Dr. Reddy's; Gate; Mylan; Teva; Apotex; Aurobindo; Roxane; Caraco/Sun; Torrent	Platelet Aggregation Inhibitors	75 mg & 300 mg tablets	PLAVIX	A-rated generics. Dr. Reddy's, Gate, Mylan, and Teva have approval for 300 mg tablets. Mylan & Dr. Reddy's have stated they have 180-days marketing exclusivity for the 300 mg tablet. Apotex, Aurobindo, Mylan, Roxane, Caraco/Sun, Teva, and Torrent have approval for 75 mg tablets.
ropinirole hydrochloride	Actavis	Antiparkinson Agents	2 mg, 4 mg, 6 mg, 8 mg, & 12 mg extended-release tablets	REQUIP XL	A-rated generic. Launch announced 05/18/2012. Actavis has 180-days shared exclusivity.
butoconazole nitrate	Perrigo	Vaginal Antiinfectives	2% vaginal cream	GYNAZOLE-1	Perrigo has 180-days marketing exclusivity and is working with KV Pharmaceutical on a collaboration to launch the product by the end of calendar year 2012. The brand product was voluntary discontinued in January 2009 due to manufacturing issues at KV Pharmaceutical.
nevirapine	Aurobindo	Antiretrovirals	50 mg/5 mL oral suspension; 200 mg tablets	VIRAMUNE	A-rated generics.
nevirapine	Cipla; Apotex; Hetero; Micro Labs; Matrix; Mylan; Prinston; Sciegen; Strides; Roxane	Antiretrovirals	200 mg tablets	VIRAMUNE	A-rated generics from all companies but Roxane; Roxane has authorized generic. Mylan announced launch 05/23/2012.

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Generic Name	Company(ies)	Therapeutic Category	Strength(s) & Dosage Form(s)	Trade Name Equivalent	Comments/Availability
voriconazole	Sandoz	Antiinfectives	200 mg vial for injection	VFEND	A-rated generic.
calcipotriene	Tolmar	Antipsoriatics	0.005% cream	DOVONEX	A-rated generic.
clindamycin phosphate in 5% dextrose	Sandoz	Antiinfectives	6 mg/mL, 12 mg/mL, & 18 mg/mL	CLEOCIN IN DEXTROSE	A-rated generic.

new indications/dosing/labeling

TRADE NAME (generic name) Company(ies)	Therapeutic Category	Description
(venlafaxine hydrochloride) Osmotica and EFFEXOR/XR (venlafaxine hydrochloride) Pfizer	Antidepressants	Approval of the addition of the following new subsection of labeling: "Drug-Laboratory Test Interactions" under Drug Interactions. This section includes the following info: false-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported in patients taking venlafaxine. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of venlafaxine therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish venlafaxine from PCP and amphetamine.
ZORTRESS (everolimus) Novartis	Immunosuppressive Agents	Approval to eliminate the requirement for the approved Risk Evaluation and Mitigation Strategy (REMS). The REMS for ZORTRESS (everolimus) was originally approved on April 10, 2010, and the most recent REMS modification was approved on November 21, 2011. The REMS consisted of a communication plan and a timetable for submission of assessments of the REMS. Because the assessment demonstrates that the communication plan has been completed and has met its goals, the FDA has determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks; therefore, a REMS for ZORTRESS is no longer required. The Medication Guide will continue to be part of the approved labeling.
PROLIA / XGEVA (denosumab) Amgen	Bone Density Regulators	Approval to change the pregnancy category from D to X.
ACTOS (pioglitazone hydrochloride); ACTOPLUS MET/XR (pioglitazone hydrochloride / metformin hydrochloride); DUETACT (pioglitazone hydrochloride / glimepiride) Takeda	Antidiabetics	Approval to eliminate the approved REMS for pioglitazone-containing products. The REMS for ACTOS (pioglitazone hydrochloride) and DUETACT (pioglitazone hydrochloride / glimepiride) was originally approved on September 9, 2009; a REMS for ACTOPLUS MET (pioglitazone hydrochloride/metformin hydrochloride) was originally approved on September 14, 2009; and a REMS for ACTOPLUS MET XR (pioglitazone hydrochloride/ metformin hydrochloride extended-release) was originally approved on May 12, 2009. The most recent REMS modification for all four pioglitazone-containing products was approved on August 4, 2011. The REMS consisted of a Medication Guide and a timetable for submission of assessments of the REMS. The FDA has determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern; therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of these pioglitazone-containing products outweigh the risks. Therefore, a REMS for these pioglitazone-containing products is no longer required. The Medication Guide will continue to be part of the approved labeling.
BIOTHRAX (anthrax vaccine adsorbed) Emergent BioDefense	Vaccines	Approval to change the dosing schedule from a five-dose primary schedule at 0, 1, 6, 12, 18 months with annual booster to a three-dose primary schedule at 0, 1, 6 months, with boosters at 12 and 18 months after initiation of the primary series, and annual boosters thereafter.
LEVEMIR (insulin detemir [rDNA origin] injection) Novo Nordisk	Antidiabetics	Approval for use in children ages two to five years with type 1 diabetes. According to Novo, LEVEMIR is the first and only basal insulin analog for use in this young patient group.
QUALAQUIN (quinine sulfate)	Antimalarials	Approval to eliminate the approved REMS. The REMS for QUALAQUIN was originally approved on June 15, 2010. The REMS consisted of a Medication Guide, a communication

TRADE NAME (generic name) Company(ies)	Therapeutic Category	Description
Mutual		plan, and a timetable for submission of assessments of the REMS. The FDA has determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern; therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of QUALAQUIN outweigh its risks. The REMS assessment received on December 15, 2011 demonstrated that the components of the communication plan have been completed, with the exception of distributing the final Dear Health Care Provider (DHCP) letter. Although the assessment suggested that understanding of the benefits and risks of the use of QUALAQUIN as a treatment for leg cramps is not optimal, FDA has determined that the risk of serious hematologic reactions is likely to be low due to declining drug use, and the agency has further determined that it is no longer necessary to include the communication plan as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks. Therefore, the FDA has determined that REMS is no longer required for QUALAQUIN. The Medication Guide will continue to be part of the approved labeling.
DYSPORT (abobotulinumtoxinA) Ipsen	Neuromuscular Blocking Agent - Neurotoxins	Approval to eliminate the approved REMS. The REMS for DYSPORT was originally approved on April 29, 2009. The REMS consisted of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS. The FDA has determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern; therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of DYSPORT outweigh the risks. Because the assessment demonstrates that the communication plan has been completed and has met its goals, FDA has determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks. Therefore, a REMS is no longer required for DYSPORT. The Medication Guide will continue to be part of the approved labeling.
STELARA (ustekinumab) Janssen	Antipsoriatics	Approval to eliminate the Medication Guide as an element of the approved REMS. The REMS for STELARA was originally approved on September 25, 2009 and the most recent REMS modification was approved on August 19, 2011. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS. The FDA has determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern; therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of STELARA outweigh the risks. The Medication Guide will continue to be part of the approved labeling. The REMS will now consist of a communication plan and a timetable for submission of assessments of the REMS.
PRADAXA (dabigatran etexilate mesylate) Boehringer Ingelheim	Anticoagulants	Approval to modify the efficacy findings in the prescribing information relative to warfarin from the RELY study and labeling text on INR control in subject's randomization to warfarin in RELY. The label now indicates that PRADAXA 150 mg twice daily was superior in reducing ischemic and hemorrhagic strokes relative to warfarin (previously the statement used the wording "PRADAXA 150 mg twice daily significantly reduced both ischemic and hemorrhagic strokes relative to warfarin").

new formulations/packaging

TRADE NAME (generic name) Company(ies)	Therapeutic Category	Indication(s)	Description
DYMISTA (azelastine hydrochloride / fluticasone propionate) Meda	Nasal Agents	Relief of Symptoms of Seasonal Allergic Rhinitis in Patients ≥ 12 Years of Age	Approval of a fixed dose combination nasal spray product containing the antihistamine azelastine (found in ASTELIN / ASTEPRO) and the corticosteroid fluticasone (found in FLONASE/VERAMYST) for patients who need both ingredients for symptomatic relief. Recommended dose is 1 spray per nostril twice daily. Available as metered dose spray containing 137 mcg/50 mcg per each 0.137 mL spray. Each bottle is 23 g and delivers 120 sprays after priming.

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TRADE NAME (generic name) Company(ies)	Therapeutic Category	Indication(s)	Description
FABIOR (tazarotene) Stiefel	Acne Products	Treatment of Acne Vulgaris in Patients ≥12 Years of Age	Approval of a 0.1% foam formulation. Dosing is a thin layer applied to the entire affected areas of the face and/or upper trunk once daily in the evening, avoiding the eyes, lips, and mucous membranes.
EFFIENT (prasugrel) Eli Lilly	Platelet Aggregation Inhibitors	Reduction of Thrombotic Cardiovascular Events (including stent thrombosis) in Patients with Acute Coronary Syndrome who are to be Managed with PCI as follows: Patients with Unstable Angina or, Non-ST-Elevation Myocardial Infarction (NSTEMI) and/or Patients with ST-Elevation Myocardial Infarction (STEMI) when Managed with either Primary or Delayed PCI	Eli Lilly announced that over the next few months, the company will be transitioning EFFIENT tablets from the original to a revised formulation, as well as introducing a new package size. The new formulation is bioequivalent to the original formulation; the only difference is that the new formulation has removed the ingredients known to cause salt-to-base conversion that occurred in the original formulation, which has no clinically relevant effect on safety or efficacy of the medication. Most important, there will be no impact on patient dosing, but there will be a change in NDC numbers as well as tablets (tablet size and imprint). The revised formulation expiration date for all packages is approximately 10 months. The revised formulation will need to be dispensed and kept in the original container (no repackaging). The desiccant should not be removed from the bottle; the tablets should not be broken. Once the bottles are opened and the seal broken, use within 30 days. The new formulation received FDA approval on April 16, 2010.
PERTZYE (pancrelipase) Digestive Care	Digestive Aids	Treatment of Exocrine Pancreatic Insufficiency (EPI) due to Cystic Fibrosis (CF) or Other Conditions	Approval of a drug already marketed but without an approved NDA. PERTZYE is a pancreatic enzyme product containing bicarbonate-buffered enteric-coated microspheres. The PERTZYE formulation was previously marketed by Digestive Care for over a decade under the trade name PANCRECARB MS-16. Available as delayed-release capsules in strengths of 8000/28750/30250 units and 16000/57500/60500 units.
OMECLAMOX-PAK (omeprazole / clarithromycin / amoxicillin) Pernix Therapeutics	Antiulcer Agents	*Helicobacter pylori* (*H. pylori*) Infection and Duodenal Ulcer Disease	Introduction announcement of a ten-day therapy pack containing omeprazole delayed-release capsules (20 mg), clarithromycin tablets (500 mg) and amoxicillin capsules (500 mg) for the treatment of *Helicobacter pylori* (*H. pylori*) infection and duodenal ulcer disease (active or one-year history) to eradicate *H. pylori* in adult patients. The medications are to be taken together, twice daily, for ten days. According to Pernix, OMECLAMOX-PAK will be available by prescription in July 2012. Originally FDA approved on February 8, 2011.
ABSORICA (isotretinoin) Cipher; Ranbaxy	Acne Products	Severe Recalcitrant Nodular Acne in Patients ≥ 12 Years of Age	Approval of another formulation of isotretinoin. ABSORICA is available as 10 mg, 20 mg, 30 mg, and 40 mg capsules. Dosing is 0.5 to 1 mg.kg/day given in two divided doses without regard to meals for 15 to 20 weeks. ABSORICA is expected to be launched in the U.S. in Q4 2012. According to Cipher, ABSORICA uses the Lidose drug delivery system, which delivers more consistent bioavailability for relatively water-insoluble compounds.
VICODIN/ES/HP (hydrocodone bitartrate / acetaminophen) Abbott	Analgesics - Opioids	Moderate to Moderately Severe Pain	On May 29, 2012, Abbott announced that in the third quarter of 2012, VICODIN will be available in the following new formulations: VICODIN 5 mg/300 mg, VICODIN ES 7.5 mg/300 mg, and VICODIN HP 10 mg/300 mg (hydrocodone bitrate / acetaminophen). This change in formulation is due to the FDA mandate to limit the strength of acetaminophen in prescription drug products to no more than 325 mg per dosage unit by January 2014.

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product safety news

Topic	Description & Links
FDA Drug Information Update – REVLIMD (lenalidomide)	FDA is informing the public of an increased risk of second primary malignancies (new types of cancer) in patients with newly-diagnosed multiple myeloma who received REVLIMD (lenalidomide). Clinical trials conducted after REVLIMD was approved showed that newly-diagnosed patients treated with REVLIMD had an increased risk of developing second primary malignancies compared to similar patients who received a placebo. Specifically, these trials showed there was an increased risk of developing acute myelogenous leukemia, myelodysplastic syndromes, and Hodgkin lymphoma. This safety information has been added to the *Warnings and Precautions* section of the REVLIMD drug label. The patient Medication Guide is also being updated to inform patients about this risk. Healthcare professionals should consider both the potential benefit of REVLIMD and the risk of second primary malignancies when deciding to treat patients with this drug, and monitor patients for this risk. Patients should contact their healthcare professional if they have any questions or concerns about REVLIMD. In April 2011, FDA announced an ongoing safety review to evaluate the possible increased risk of second primary malignancies with REVLIMD. FDA performed a comprehensive review of this safety issue. For more information visit: http://www.fda.gov/Drugs/DrugSafety/ucm302939.htm
FDA MedWatch - Monthly Safety Labeling Changes includes 43 Products with Revisions to Prescribing Information	The MedWatch April 2012 Safety Labeling Changes posting includes 43 products with safety labeling changes to the following sections: BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and PATIENT PACKAGE INSERT. The following drugs had modifications to the BOXED WARNINGS, CONTRAINDICATIONS and WARNINGS sections: ACEON (perindopril erbumine); ALTACE (ramipril); ATACAND (candesartan cilexetil); SPORANOX (itraconazole); ZORTRESS (everolimus); ADVICOR (niacin extended-release/lovastatin); ALTOPREV (lovastatin extended-release); AMTURNIDE (aliskiren / amlodipine / hydrochlorothiazide); PREMARIN (conjugated estrogens, USP); TEKAMLO (aliskiren/amlodipine); TEKTURNA (aliskiren); TEKTURNA HCT (aliskiren/hydrochlorothiazide); VAGIFEM (estradiol); VALTURNA (aliskiren/valsartan); VIRACEPT (nelfinavir mesylate); BEYAZ (drospirenone/ethinyl estradiol/levomefolate calcium); CIMZIA (certolizumab pegol); KRYSTEXXA (pegloticase); LEVAQUIN (levofloxacin); LEVEMIR (insulin detemir [rDNA origin]); NEUPRO (rotigotine); NUTROPIN (somatropin [rDNA origin]); PRANDIMET (repaglinide/metformin HCl); SAFYRAL (drospirenone/ethinyl estradiol/levomefolate calcium); SUTENT (sunitinib malate); SYNAGIS (palivizumab); TARCEVA (erlotinib); VICTOZA (liraglutide [rDNA]); VOTRIENT (pazopanib); XGEVA (denosumab); YASMIN (drospirenone/ethinyl estradiol); YAZ (drospirenone/ethinyl estradiol); and ZEGERID (omeprazole/sodium bicarbonate). The "Summary Page" provides a listing of drug names and safety labeling sections revised: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm302285.htm
FDA MedWatch - ZITHROMAX (azithromycin): FDA Statement on Risk of Cardiovascular Death	FDA notified healthcare professionals that it is aware of the study published in the *New England Journal of Medicine* May 17, 2012 (http://www.nejm.org/doi/full/10.1056/NEJMoa1003833?source=govdelivery) reporting a small increase in cardiovascular deaths, and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin (trade name ZITHROMAX) compared to persons treated with amoxicillin, ciprofloxacin, or no drug. FDA is reviewing the results from this study and will communicate any new information on azithromycin and this study or the potential risk of QT interval prolongation after the agency has completed its review. Patients taking azithromycin should not stop taking their medicine without talking to their healthcare professional. Healthcare professionals should be aware of the potential for QT interval prolongation and heart arrhythmias when prescribing or administering macrolides. Read the MedWatch safety alert, including a link to the Drug Safety Communication at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm304503.htm
FDA Drug Information Update - FDA Drug Safety Communication: Revised Recommendations for Cardiovascular Monitoring and Use of Multiple Sclerosis drug GILENYA (fingolimod)	FDA has completed its evaluation of a report of a patient who died after the first dose of multiple sclerosis drug GILENYA (fingolimod). The agency also has evaluated additional clinical trial and postmarket data for GILENYA, including reports of patients who died of cardiovascular events or unknown causes. FDA could not definitively conclude that GILENYA was related to any of the deaths. However, based on its reevaluation of the data, FDA remains concerned about the cardiovascular effects of GILENYA after the first dose. Data show that, although the maximum heart rate lowering effect of GILENYA usually occurs within 6 hours of the first dose, the maximum effect may occur as late as 20 hours after the first dose in some patients. For this reason, GILENYA is now contraindicated in patients with certain pre-existing or recent (within last 6 months) heart conditions or stroke, or who are taking certain antiarrhythmic medications. FDA continues to recommend that all patients starting GILENYA be monitored for signs of a slow heart rate (bradycardia) for at least 6 hours after the first dose. FDA is now recommending hourly pulse and blood pressure measurement for all patients starting GILENYA. Electrocardiogram (ECG or EKG) testing should be performed prior to dosing and at the end of the observation period. Cardiovascular monitoring should continue until any symptoms resolve. In addition, FDA is now also recommending that the time of cardiovascular monitoring be extended past 6 hours in patients who are at higher risk for or who may not tolerate bradycardia. Extended monitoring should include continuous ECG monitoring that continues overnight. For more information see: http://www.fda.gov/Drugs/DrugSafety/ucm303192.htm

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FDA Drug Information Update - FDA advises healthcare providers to visually inspect Hospira Carpuject pre-filled cartridges for overfill	FDA is alerting healthcare providers of a potential safety risk in some Carpuject pre-filled cartridges manufactured by Hospira, Inc. The pre-filled cartridges containing the products listed below may be overfilled by at least twice the expected amount, resulting in potential overdose. FDA is advising healthcare providers to follow the instructions provided with the medication and visually inspect and confirm that the Carpuject pre-filled cartridge contains the labeled fill volume before dispensing and again before administering to patients. For more information see: http://www.fda.gov/Drugs/DrugSafety/ucm304902.htm
FDA MedWatch - Dialysate Concentrates Used in Hemodialysis: Safety Communication - Alkali Dosing Errors	FDA is notifying health care providers to consider the presence and quantity of acetate, citrate, and/or acetic acid in dialysate concentrates when determining the patients' dialysate prescription. The FDA received a complaint describing alkali dosing errors that occurred during hemodialysis using dialysate concentrates containing acetic acid and acetate. When metabolized, these potential sources of alkali can contribute to elevated bicarbonate levels in patients undergoing hemodialysis. This can contribute to metabolic alkalosis, which is a significant risk factor associated with cardiopulmonary arrest, low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia. Health care providers should review the dialysate acid concentrate labeling for the specific concentrate that they prescribe to determine the components that can contribute to the patient's overall bicarbonate levels. The levels of acetate, citrate and/or acetic acid vary by formulation and by manufacturer. Be aware that metabolic alkalosis (pre-dialysis serum bicarbonate levels > or = to 27 mEq/L) has been associated with a higher risk of death in hemodialysis patients. Read the MedWatch safety alert, including a link to the FDA Safety Communication, at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm305630.htm
FDA HIV/AIDS Update - PREZISTA (darunavir) label update	Updates to the PREZISTA (darunavir) package insert were approved on June 1, 2012 and include the following: (1) Addition of acute generalized exanthematous pustulosis (an acute skin eruption of characterized by numerous small, sterile pustules) to the WARNINGS and PRECAUTIONS, Severe Skin Reaction and ADVERSE REACTIONS, Postmarketing Experience sections; and (2) Revisions to DRUG INTERACTIONS, Established and Other Potentially Significant Drug Interactions and CLINICAL PHARMACOLOGY, Pharmacokinetics sections to include boceprevir drug-drug interaction information. Specifically, Concomitant administration of Prezista/ritonavir and boceprevir resulted in reduced steady-state exposures to darunavir and boceprevir. It is not recommended to co-administer boceprevir and Prezista/ritonavir.
FDA Drug Information Update - FDA warns consumers about counterfeit version of Teva's ADDERALL	The FDA warned consumers and health care professionals about a counterfeit version of Teva Pharmaceutical Industries' ADDERALL 30 milligram tablets that is being purchased on the Internet. ADDERALL, which is approved to treat attention deficit hyperactivity disorders (ADHD) and narcolepsy, is a prescription drug classified as a controlled substance – a class of drugs for which special controls are required for dispensing by pharmacists. FDA's preliminary laboratory tests revealed that the counterfeit version of Teva's ADDERALL 30 mg tablets contained the wrong active ingredients. ADDERALL contains four active ingredients – dextroamphetamine saccharate, amphetamine aspartate, dextroamphetamine sulfate, and amphetamine sulfate. Instead of these active ingredients, the counterfeit product contained tramadol and acetaminophen, which are ingredients in medicines used to treat acute pain. For more information, visit: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm305932.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=teva%20adderall&utm_content=1. The FDA also issued a MedWatch regarding this. Read the MedWatch safety alert, including a link to the FDA Press Release, at: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm306041.htm

pipeline news

Upcoming PDUFA Action Dates and/or PDUFA News

TRADE NAME (generic name)	Company(ies)	Type	PDUFA Date	Potential Use(s)	Comments
MENHIBRIX (Hib-MenCY)	GlaxoSmithKline	sBLA	2012-Jun 1	Immunization of Infants & Toddlers against Meningococcal Serogroups C&Y and H. Influenzae Type b (Hib) Diseases at 2, 4, 6 and 12 to 15 months of age	New Formulation; Intramuscular
TALTORVIC (ridaforolimus)	Merck; Ariad	NDA	2012-Jun 5	Treatment of Adult and Pediatric Patients (aged 13 through 17 years with weight over 100 lb or 45.4 kg) with Metastatic Soft Tissue Sarcoma or Bone Sarcoma as a Maintenance Therapy for Patients who have Completed at Least 4	New Molecular Entity; Oral

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Upcoming PDUFA Action Dates and/or PDUFA News					
TRADE NAME (generic name)	Company(ies)	Type	PDUFA Date	Potential Use(s)	Comments
				cycles of Chemotherapy without Evidence of disease Progression	
OMNITARG (pertuzumab)	Roche; Genentech; Chugai	NDA	2012-Jun 8	In Combination with Trastuzumab and Docetaxel Chemotherapy for HER2+ Metastatic or Locally Recurrent, Unresectable Breast Cancer in Patients who have not Received Previous Treatment or whose Disease has Relapsed after Adjuvant Therapy	New Molecular Entity; Intravenous
AUBAGIO (teriflunomide)	Sanofi Aventis	NDA	2012-Jun 8	Relapsing Remitting Multiple Sclerosis (RRMS)	New Molecular Entity; Oral
HORIZANT (gabapentin enacarbil ER)	GlaxoSmithKline; XenoPort	sNDA	2012-Jun 9	Management of Postherpetic Neuralgia (PHN) in Adults	New Indication; Oral
VYNDAQEL (tafamidis meglumine)	FoldRx; Pfizer	NDA	2012-Jun 15	Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP)	New Molecular Entity; Oral
TRUVADA (emtricitabine / tenofovir disoproxil fumarate)	Gilead Sciences	sNDA	2012-Jun 15	Pre-Exposure Prophylaxis (PrEP) to Reduce the Risk of HIV-1 Infection among Uninfected Adults	New Indication; Oral
MOXDUO IR (morphine / oxycodone immediate-release)	QRxPharma; Actavis	NDA	2012-Jun 25	Moderate to Severe Acute Pain	New Formulation; Oral
LORQESS (lorcaserin)	Arena; Eisai	NDA	2012-Jun 27	Weight Management	New Molecular Entity; Oral
ELIQUIS (apixaban)	Bristol-Myers Squibb; Pfizer	NDA	2012-Jun 28	Prevention of Stroke & Systemic Embolism in Atrial Fibrillation (AF)	New Molecular Entity; Oral
BETANIS (mirabegron)	Astellas	NDA	2012-Jun 29	Overactive Bladder (OAB)	New Molecular Entity; Oral
XARELTO (rivaroxaban)	Bayer; Johnson & Johnson	sNDA	2012-Jun 29	Reduce the Risk of Thrombotic Cardiovascular Events in Patients with Acute Coronary Syndrome (ACS)	New Indication; Oral
HUMIRA (adalimumab)	Abbott	sNDA	2012-Q2	Ulcerative Colitis (UC)	New Indication; Subcutaneous
ERBITUX (cetuximab)	Bristol Myers Squibb	sNDA	2012-Q2	First-line Treatment of Non-Small-Cell Lung Cancer (NSCLC)	New Indication; Intravenous
ESOMEZOL (esomeprazole strontium)	Hanmi	NDA	2012-Q2	Gastric Ulcer	New Formulation; Oral
NEXIUM (esomeprazole)	AstraZeneca	sNDA	2012-Q2	Peptic Ulcer Bleeding	New Indication; Intravenous

Upcoming Patent Expirations/Generic Launches			
Trade Name (generic name); Company	Therapeutic Uses	Estimated Sales (USD)	Anticipated Availability
LESCOL XL† (fluvastatin sodium extended-release); Novartis	Hyperlipidemia	$97 million	June 2012
CLARINEX† (desloratadine); Schering/Merck	Allergies; Hives	$659 million [Global]	July 2012
CLARINEX REDITABS† (desloratadine orally disintegrating tablets); Schering/Merck			
CLARINEX-D 24 HOUR† (desloratadine/ pseudoephedrine); Schering/Merck	Allergies; Congestion		
CLARINEX-D 12 HOUR† (desloratadine/ pseudoephedrine); Schering/Merck			
TRICOR† (fenofibrate); Abbott	Hyperlipidemia	$1.3 billion	July 2012

Comments†:

- LESCOL/ LESCOL XL: Launch type appears to be exclusive; however, a competitive launch is feasible pending certain FDA determinations.

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Upcoming Patent Expirations/Generic Launches			
Trade Name (generic name); Company	Therapeutic Uses	Estimated Sales (USD)	Anticipated Availability

- CLARINEX and CLARINEX-D products may be approved and available as Over-the-Counter (OTC) products prior to the launch of generic alternatives. Several manufacturers have received FDA approval for generic CLARINEX [Orchid, Lupin, Sun, and Sandoz]. Due to a patent litigation settlement, these manufacturers will be able to launch their respective generic on or after July 1, 2012. Dr. Reddy is the only manufacturer listed to have received FDA approval for its generic version of CLARINEX REDITABS on July 12, 2010; however, due to patent litigation settlements, multiple generic manufacturers [Dr. Reddy, Orchid, and Zydus] are expected to launch their respective generic version on or after January 1, 2012. Dr. Reddy also received FDA approval for its generic version of CLARINEX-D 24 HOUR on April 26, 2011. Estimated U.S. Sales figures of $659 million [global] include all CLARINEX and CLARINEX-D products.
- TRICOR: Lupin's generic version of TRICOR was approved on December 23, 2011. A competitive launch is not certain at this time; although it has been reported that multiple manufacturers are anticipated to launch. Generic availability for TRICOR 48 mg is uncertain. Sales figure includes both TRICOR and TRILIPIX products.

Products Receiving Complete Response Letters (CRL) or Refuse-to-File Letters (RTF)			
TRADE NAME (generic name) Company(ies)	Therapeutic Category	Proposed Use(s)	Comments
ADASUVE (loxapine) Alexza	Antipsychotics / Antimanic Agents	Acute Treatment of Agitation Associated with Schizophrenia or Bipolar I Disorder in Adults	In the CRL, the FDA noted, "During a recent inspection of the Mountain View, CA manufacturing facility for this application, our field investigator conveyed deficiencies to the representative of the facility. Satisfactory resolution of these deficiencies is required before this application may be approved." Alexza believes the deficiencies are medical device specific and readily addressable. Alexza plans to meet with the FDA to gain a better understanding of the specific deficiencies and this meeting will be scheduled as soon as practical. Alexza looks forward to working to resolve the remaining issues in a timely manner. There were no new clinical or safety issues identified and there were no other deficiencies outlined in the CRL. With respect to the ADASUVE Risk Evaluation and Mitigation Strategy (REMS), the CRL stated that discussions can continue on the proposed REMS after the response to the action letter has been submitted. The CRL also contained comments on Alexza's draft product labeling. Alexza believes that there is substantial agreement between Alexza and the FDA on the REMS and product labeling.
PREZISTA (darunavir) Janssen	Antiretrovirals	Treatment of Human Immunodeficiency Virus (HIV-1) in Treatment-Naive and Treatment-Experienced Adult Patients	FDA issued a CRL for a sNDA for an 800 mg tablet of PREZISTA. Janssen is developing the 800 mg tablet dosage strength to allow patients taking PREZISTA once daily to reduce the number of PREZISTA tablets by half, taking one 800 mg tablet instead of two 400 mg tablets once a day with ritonavir 100 mg and other antiretroviral medications. The sNDA for the 800 mg tablet strength was submitted in January 2012. Janssen is evaluating the FDA's letter and will respond to the agency as quickly as possible. The company does not expect additional clinical trials will be required to address the FDA's feedback in the CRL.

FDA and/or Pharma Filings/Actions				
TRADE NAME (generic name) Company(ies)	Therapeutic Category	Dosage Form(s) or Route(s) of Administration	Proposed Use(s)	Comments
ZOHYDRO (hydrocodone bitartrate extended-release) Zogenix	Analgesics and Anesthetics	Oral	Chronic Pain	Zogenix submitted a NDA to the FDA for ZOHYDRO, a novel, oral, single-entity (without acetaminophen) extended-release formulation of various strengths of hydrocodone intended for administration every 12 hours for around the clock management of moderate to severe chronic pain. Will be a DEA schedule II controlled substance and have a REMS.

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FDA and/or Pharma Filings/Actions				
TRADE NAME (generic name) Company(ies)	**Therapeutic Category**	**Dosage Form(s) or Route(s) of Administration**	**Proposed Use(s)**	**Comments**
XARELTO (rivaroxaban) Janssen	Anticoagulants	Oral	Treatment of Deep Vein Thrombosis or Pulmonary Embolism; Prevention of Recurrent Venous Thromboembolism	Janssen submitted sNDAs to the FDA seeking approval for the use of XARELTO to treat patients with deep vein thrombosis (DVT) or pulmonary embolism (PE) and prevention of recurrent venous thromboembolism (VTE).
ARCALYST (rilonacept) Regeneron	Analgesics and Anesthetics	Subcutaneous Injection	Gout	The FDA's Arthritis Advisory Committee voted against approval of ARCALYST or the proposed indication for the prevention of gout flares in patients initiating uric acid-lowering therapy.
(tofacitinib) Pfizer	Analgesics and Anesthetics	Oral	Rheumatoid Arthritis (RA)	The FDA's Arthritis Advisory Committee voted 8-2 to recommend approval of tofacitinib for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).
XARELTO (rivaroxaban) Janssen	Anticoagulants	Oral	Acute Coronary Syndrome (ACS)	Janssen submitted a sNDA to the FDA seeking approval for the use of XARELTO to reduce the risk of stent thrombosis in patients with ACS.
(emtricitabine / tenofovir disoproxil fumarate / elvitegravir / cobicistat) Gilead	Antiretrovirals	Oral	HIV-1 Infection	The FDA's Antiviral Drugs Advisory Committee voted 13 to 1 to recommend approval of a 'Quad' tablet from Gilead for the treatment of a specific population of adults infected with HIV-1.
TRUVADA (emtricitabine / tenofovir disoproxil fumarate) Gilead	Antiretrovirals	Oral	Pre-Exposure Prophylaxis (PrEP) to Reduce the Risk of HIV-1 Infection among Uninfected Adults	The FDA's Antiviral Drugs Advisory Committee voted to support approval of once-daily oral TRUVADA to reduce the risk of HIV-1 infection among uninfected adults, an HIV prevention strategy called pre-exposure prophylaxis or PrEP. In response to questions posed to the committee, members voted 19 to 3 in favor of approval for TRUVADA for PrEP in men who have sex with men; 19 to 2 (with 1 abstaining) in support of use in HIV-uninfected partners in serodiscordant couples; and 12 to 8 (with 2 abstaining) in other individuals at risk for acquiring HIV through sexual activity.
BG-12 (dimethyl fumarate) Biogen Idec	Misc. Psychotherapeutic & Neurologic Agents	Oral	Multiple Sclerosis (MS)	The FDA has accepted Biogen Idec's NDA for review and granted the company a standard review (10 months) timeline.
(enzalutamide) Medivation; Astellas	Antineoplastics & Adjunctive Therapies	Oral	Castration-Resistant Prostate Cancer	Medivation submitted a NDA to the FDA for enzalutamide (formerly MDV3100). The compound has been studied in patients with castration-resistant prostate cancer who have received docetaxel therapy. Requested priority review.
(regorafenib) Bayer	Antineoplastics & Adjunctive Therapies	Oral	Metastatic Colorectal Cancer (mCRC)	Bayer submitted a NDA to the FDA seeking approval for the oral multi-kinase inhibitor regorafenib for the treatment of patients with metastatic colorectal cancer (mCRC).
XARELTO (rivaroxaban) Janssen	Anticoagulants	Oral	Acute Coronary Syndrome (ACS)	The FDA's Cardiovascular and Renal Drugs Advisory Committee voted against the approval of XARELTO to reduce the risk of secondary cardiovascular events in patients with ACS in combination with standard antiplatelet therapy.

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FDA and/or Pharma Filings/Actions				
TRADE NAME (generic name) Company(ies)	**Therapeutic Category**	**Dosage Form(s) or Route(s) of Administration**	**Proposed Use(s)**	**Comments**
VYNDAQEL (tafamidis meglumine) Pfizer; FoldRx	Endocrine & Metabolic Drugs	Oral	Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP)	The FDA's Peripheral and Central Nervous System Drugs Advisory Committee did not find substantial evidence of efficacy on a clinical endpoint for VYNDAQEL. The Committee then voted 13-4 that the data provide substantial evidence of efficacy for a surrogate endpoint that is reasonably likely to predict a clinical benefit.
KYNAMRO (mipomersen sodium) Genzyme; Isis	Antihyperlipidemics	Subcutaneous Injection	Homozygous Familial Hyper-cholesterolemia (HoFH)	FDA accepted for filing the NDA for KYNAMRO for the treatment of patients with HoFH. Genzyme submitted an application for U.S. marketing approval of KYNAMRO for the treatment of patients with HoFH in March 2012. The application will be subject to a standard review and will have a PDUFA date of January 29, 2013.
(human 4-factor prothrombin complex concentrate) CSL Behring	Hematological Agents	Intravenous Injection	Reversal of Vitamin K-Antagonist Therapy	FDA accepted for standard review the BLA for human 4-factor prothrombin complex concentrate (PCC) for the urgent reversal of vitamin K-antagonist therapy (i.e., warfarin) in patients with acute major bleeding. If approved by the FDA, the CSL Behring 4-factor PCC would be the first agent of its kind available in the U.S.
(cabozantinib) Exelixis	Antineoplastics & Adjunctive Therapies	Oral	Metastatic Medullary Thyroid Cancer (MTC)	Exelixis completed the filing of its rolling NDA with the FDA for cabozantinib as a treatment for patients with progressive, unresectable, locally advanced, or metastatic MTC. The NDA was submitted under the FDA's fast track designation. As part of the NDA filing, Exelixis has requested priority review designation from the FDA.
PROMACTA (eltrombopag) Ligand; GlaxoSmithKline	Hematopoietic Growth Factors	Oral	Thrombocytopenia in Adults with Chronic Hepatitis C Infection (HCV)	GlaxoSmithKline submitted a sNDA to the FDA for PROMACTA as a treatment for thrombocytopenia in adult patients with chronic hepatitis C infection to enable the initiation of interferon-based therapy and to optimize interferon-based therapy.
(canagliflozin) Janssen	Antidiabetics	Oral	Type 2 Diabetes Mellitus (DM)	Janssen submitted a NDA to the FDA seeking approval for the use of canagliflozin, an investigational, oral, once-daily, selective sodium glucose co-transporter 2 (SGLT2) inhibitor, for the treatment of adult patients with type 2 diabetes.

ANDA Filings and/or Patent Litigation News		
Trade Name (generic name) Company	**Therapeutic Use(s)**	**Description/Comments**
HECTOROL (doxercalciferol) Genzyme	Secondary Hyperparathyroidism in Patients with Chronic Kidney Disease (CKD)	Genzyme filed a patent infringement lawsuit against Cobrek Pharmaceuticals on April 20, 2012 in the Northern District of Illinois. The suit claims infringement of U.S. Patent No. 5,602,116 ("Method for Treating and Preventing Secondary Hyperparathyroidism," issued February 11, 1997) following a Paragraph IV certification as part of Cobrek's filing of an ANDA to manufacture a generic version of Genzyme's HECTOROL.
RENVELA (sevelamer carbonate) Genzyme	Control of Serum Phosphorus in Patients with Chronic Kidney Disease on Dialysis	Genzyme filed a patent infringement lawsuit against Invagen Pharmaceuticals on April 19, 2012 in the Eastern District of New York. The suit claims infringement of U.S. Patent No. 5,667,775 ("Phosphate-Binding Polymers for Oral Administration," issued on September 16, 1997) following a Paragraph IV certification as part of Invagen's filing of an ANDA to manufacture a generic version of Genzyme's RENVELA.

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ANDA Filings and/or Patent Litigation News		
Trade Name (generic name) Company	**Therapeutic Use(s)**	**Description/Comments**
OXYCONTIN (oxycodone hydrochloride controlled-release) Purdue	Moderate to Severe Pain	Purdue Pharma filed a patent infringement lawsuit against Watson on April 19, 2012 in the Southern District of New York. The suit claims infringement of U.S. Patent No. 8,114,383 ("Abuse-Proofed Dosage Form," issued February 14, 2012 following a Paragraph IV certification as part of Watson's filing of an ANDA to manufacture a generic version of Purdue Pharma's OXYCONTIN.
LIALDA (mesalamine delayed-release) Shire	Induction of Remission of Ulcerative Colitis (UC)	Shire filed a patent infringement lawsuit against Watson on May 8, 2012 in the Southern District of Florida. The suit claims infringement of U.S. Patent No. 6,773,720 ("Mesalamine Controlled Release Oral Pharmaceutical Compositions," issued August 10, 2004) following a Paragraph IV certification as part of Watson's filing of an ANDA to manufacture a generic version of Shire's LIALDA (mesalamine).
ABILIFY (aripiprazole) Otsuka	Schizophrenia; Bipolar Disorder; Irritability Associated with Autism; Adjunct to Major Depressive Disorder Treatment	Otsuka announced that the U.S. Court of Appeals for the Federal Circuit issued its judgment dated May 7, 2012 in favor of Otsuka Pharmaceutical Co., Ltd. in its patent litigation against several companies seeking FDA approval to market generic copies of ABILIFY. The Federal Circuit affirmed the only issue on appeal from the district court's decision, holding that the asserted claims of U.S. Patent No. 5,006,528 covering aripiprazole, the active ingredient in ABILIFY, are valid, thus maintaining patent and regulatory protection for ABILIFY in the United States until at least April 20, 2015.
STAXYN (vardenafil hydrochloride) Bayer	Erectile Dysfunction (ED)	Bayer filed a patent infringement lawsuit against Watson on April 25, 2012 in the District Court of Delaware. The suit claims infringement of U.S. Patent Nos. 6,362,178 ("2-phenyl Substituted Imidazotriazinones as Phosphodiesterase Inhibitors," issued March 26, 2002) and 7,696,206 (same title, issued April 13, 2010) following a Paragraph IV certification as part of Watson's filing of an ANDA to manufacture a generic version of plaintiffs' STAXYN (vardenafil hydrochloride).
ZEMPLAR (paricalcitol) Abbott	Prevention & Treatment of Secondary Hyperparathyroidism Associated with Chronic Kidney Disease Stages 3 & 4	Abbott filed a patent infringement lawsuit against Agila on April 25, 2012 in the District Court of Delaware. The suit claims infringement of U.S. Patent Nos. 6,136,799 ("Cosolvent Formulations," issued October 24, 2000), 6,361,758 (same title, issued March 26, 2002), and 5,597,815 ("Prevention of Hyperphosphatemia in Kidney Disorder Patients," issued January 28, 1997) following a Paragraph IV certification as part of Agila's filing of an ANDA to manufacture a generic version of Abbott's ZEMPLAR (paricalcitol).
TARCEVA (erlotinib) OSI	Locally Advanced or Metastatic Non-Small Cell Lung Cancer; Locally Advanced, Unresectable, or Metastatic Pancreatic Cancer	OSI Pharmaceuticals filed a patent infringement lawsuit against Roxane on April 20, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent Nos. RE41,065 ("Alkynyl and Azido-Substituted 4-Anilinoquinazoline," issued May 5, 1998), 6,900,221 ("Stable Polymorph on N-(3-Ethynylpheny1)-6, 7-Bis(2MethoxyEthoxy)-4-Quinazolinamine Hydrochloride, Methods of Production, and Pharmaceutical Uses Thereof," issued May 31, 2005), and 7,087,613 ("Treating Abnormal Cell Growth With A Stable Polymorph on N-(3-Ethynylpheny1)-6,7-Bis(2MethoxyEthoxy)-4-Quinazolinamine Hydrochloride," issued August 8, 2006) following a Paragraph IV certification as part of Roxane's filing of an ANDA to manufacture a generic version of OSI's Tarceva (erlotinib).
STALEVO (levodopa / carbidopa / entacapone) ORION	Parkinson's Disease	Orion filed a patent infringement lawsuit against Mylan on April 26, 2012 in the District Court of Delaware. The suit claims infringement of U.S. Patent Nos. 5,446,194 ("Pharmacologically active catechol derivatives," issued August 29, 1995), 6,500,867 ("Pharmaceutical Composition Comprising Entacapone, Levodopa, and Carbidopa," issued December 31, 2002), and 6,797,732 (same title, issued September 28, 2004) following a Paragraph IV certification as part of Mylan's filing of an ANDA to manufacture a generic version of Orion's STALEVO (marketed by Novartis in the U.S.) (entacapone, levodopa, and carbidopa).
ATELVIA (risedronate sodium) Warner Chilcott	Treatment of Postmenopausal Osteoporosis	Warner Chilcott filed a patent infringement lawsuit against Ranbaxy on April 26, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent Nos. 7,645,459 ("Dosage Forms of Bisphosphonates," issued January 12, 2010) and 7,645,460 ("Dosage Forms of Risedronate" issued January 12, 2010) following a Paragraph IV certification as part of Ranbaxy's filing of an ANDA to manufacture a generic version of Warner Chilcott's ATELVIA (risedronate sodium delayed-release).
ABILIFY	Schizophrenia; Bipolar	Otsuka filed a patent infringement lawsuit against Amneal on April 26, 2012 in the

ANDA Filings and/or Patent Litigation News		
Trade Name (generic name) Company	**Therapeutic Use(s)**	**Description/Comments**
(aripiprazole) Otsuka	Disorder; Irritability Associated with Autism; Adjunct to Major Depressive Disorder Treatment	District Court of New Jersey. The suit claims infringement of U.S. Patent No. 6,977,257 ("Aripiprazole Oral Solution," issued December 20, 2005) following a Paragraph IV certification as part of Amneal's filing of an ANDA to manufacture a generic version of Otsuka's ABILIFY (aripiprazole).
AZILECT (rasagiline) Teva	Parkinson's Disease	Teva Neuroscience filed a patent infringement lawsuit against Sandoz on April 26, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent No. 5,453,446 ("Use of the R-Enantiomers of N-Propargyl 1-Aminoindan Compounds for Treating Parkinson's Disease," issued September 26, 1995) following a Paragraph IV certification as part of Sandoz's filing of an ANDA to manufacture a generic version of Teva's AZILECT (rasagiline mesylate).
LIDODERM (lidocaine topical patch) Endo	Relief of Pain Associated with Post-Herpetic Neuralgia	Noven confirmed that it has filed an ANDA with the FDA seeking approval to market its lidocaine topical patch 5%. Noven's lidocaine topical patch 5% is a generic version of Endo Pharmaceuticals' LIDODERM. On May 15, 2012, pursuant to the Hatch-Waxman Act, Noven notified Endo and its partners (Teikoku Seiyaku Co., Ltd. and Teikoku Pharma USA) that Noven's ANDA had been accepted for review by the FDA and includes a paragraph IV certification.
LO LOESTRIN FE (norethindrone acetate/ ethinyl estradiol / ferrous fumarate) Warner Chilcott	Prevention of Pregnancy	Warner Chilcott filed a patent infringement lawsuit against Watson on May 16, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent Nos. 5,552,394 ("Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy," issued September 3, 1996) and 7,704,984 ("Extended Estrogen Dosing Contraceptive Regimen" issued April 27, 2010) following a Paragraph IV certification as part of Watson's filing of an ANDA to manufacture a generic version of Warner Chilcott's LO LOESTRIN FE (norethindrone acetate and ethinyl estradiol tablets, and ethinyl estradiol and ferrous fumarate tablets).
PREZISTA (darunavir) Janssen	HIV-1 Infection	Janssen filed a patent infringement lawsuit against Lupin on May 10, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent No. RE42,889 ("a- and β-Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors," issued November 1, 2011) following a Paragraph IV certification as part of Lupin's filing of an ANDA to manufacture a generic version of Janssen's PREZISTA (darunavir).
GRALISE (gabapentin) Depomed	Management of Post-Herpetic Neuralgia	Depomed filed a patent infringement lawsuit against Zydus on May 9, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent Nos. 6,340,475 ("Extending the Duration of Drug Release Within the Stomach During the Fed Mode," issued January 22, 2002), 6,488,962 ("Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms," issued December 3, 2002), 6,635,280 ("Extending the Duration of Drug Release Within the Stomach During the Fed Mode," issued October 21, 2003), 6,723,340 ("Optimal Polymer Mixtures for Gastric Retentive Tablets," issued April 20, 2004), 7,438,927 ("Methods of Treatment Using a Gastric Retained Gabapentin Dosage," issued October 21, 2008) and 7,731,989 ("Gastric Retained Gabapentin Dosage Form," issued June 8, 2010) following a Paragraph IV certification as part of Zydus' filing of an ANDA to manufacture a generic version of Depomed's GRALISE (gabapentin).
APLENZIN (bupropion) Valeant	Major Depressive Disorder (MDD)	Valeant filed a patent infringement lawsuit against Sandoz on April 30, 2012 in the District Court of Delaware. The suit claims infringement of U.S. Patent Nos. 7,241,805 ("Modified Release Formulations of a Bupropion Salt," issued July 10, 2007), 7,569,610 (same title, issued August 4, 2009), 7,572,935 (same title, issued August 11, 2009), 7,585,897 (same title, issued September 8, 2009), 7,645,802 ("Bupropion Hydrobromide and Therapeutic Applications," issued January 12, 2010), 7,649,019 ("Modified Release Formulations of a Bupropion Salt," issued January 19, 2010), 7,662,407 (same title, issued February 16, 2010), 7,671,094 ("Bupropion Hydrobromide and Therapeutic Applications," issued March 2, 2010), and 7,553,992 ("Modified Release Formulations of a Bupropion Salt," issued June 30, 2009) following a Paragraph IV certification as part of Sandoz's filing of an ANDA to manufacture a generic version of Valeant's APLENZIN ER (bupropion).

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ANDA Filings and/or Patent Litigation News		
Trade Name (generic name) Company	**Therapeutic Use(s)**	**Description/Comments**
TESTIM (testosterone) Auxilium	Male Hypogonadism	Auxilium filed a patent infringement lawsuit against Watson on May 23, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent Nos. 7,320,968 ("Pharmaceutical Composition," issued January 22, 2008), 7,608,605 (same title, issued October 27, 2009), 7,608,606 (same title, issued October 27, 2009), 7,608,607 (same title, issued October 27, 2009), 7,608,608 (same title, issued October 27, 2009), 7,608,609 (same title, issued October 27, 2009), 7,608,610 (same title, issued October 27, 2009), 7,935,690 (same title, issued May 3, 2011), 8,063,029 (same title, issued November 22, 2011), and 8,178,518 (same title, issued May 15, 2012) following a Paragraph IV certification as part of Watson's filing of an ANDA to manufacture a generic version of Auxilium's TESTIM (transdermal testosterone gel).
LIDODERM (lidocaine topical patch) Endo	Relief of Pain Associated with Post-Herpetic Neuralgia	Watson has entered into an agreement with Endo Pharmaceuticals Inc. and Teikoku Seiyaku Co., Ltd to settle all outstanding patent litigation related to Watson's generic version of LIDODERM. The agreement allows Watson to launch its lidocaine topical patch 5% product on September 15, 2013, if approved by the FDA. The license will be exclusive as to an authorized generic version of LIDODERM until the earlier of a third party generic launch or seven and one half months after Watson's launch of its generic product. Endo will receive 25% of the gross profit generated on Watson's sales of its generic version of LIDODERM during Watson's period of exclusivity. Additionally, under the terms of the agreement, Watson will receive and be able to distribute equal amounts of branded LIDODERM product from Endo valued at a total of up to approximately $96 million during the first eight months of 2013. In the event that Watson has not received FDA approval to launch its own lidocaine topical patch 5% by January 1, 2014, Watson will receive additional quantities of branded LIDODERM product to distribute valued at up to approximately $80 million in 2014 over a period of twelve months and in the event that Watson has not received FDA approval to launch its own lidocaine topical patch 5% by January 1, 2015, up to approximately $64 million over a period of nine months in 2015. Watson's availability of brand product would cease upon the launch of any generic version of LIDODERM.
ORTHO TRI-CYCLEN LO (norgestimate / ethinyl estradiol) Janssen	Prevention of Pregnancy	Janssen filed a patent infringement lawsuit against Haupt Pharma, on May 22, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent No. 6,214,815 ("Triphasic Oral Contraceptive," issued April 10, 2001) following a Paragraph IV certification as part of Sun's filing of an ANDA to manufacture a generic version of Janssen's ORTHO TRI-CYCLEN LO (norgestimate and ethinyl estradiol).
ACETADOTE (acetylcysteine) Cumberland	Prevent or Lessen Hepatic Injury after Ingestion of a Potentially Hepatotoxic Quantity of Acetaminophen	Cumberland filed patent infringement lawsuits against InnoPharma, Mylan, and Paddock on May 17, 2012 in the District Court of Delaware and the Northern District of Illinois. The suits claim infringement of U.S. Patent No. 8,148,356 ("Acetylcysteine Composition and Uses Therefor," issued April 3, 2012) following a Paragraph IV certification as part of defendants' filing of an ANDA to manufacture a generic version of Cumberland's ACETADOTE (N-acetylcysteine injection).
EXFORGE HCT (amlodipine / valsartan / hydrochlorothiazide) Novartis	Hypertension	Novartis filed patent infringement lawsuits against Lupin and Torrent on May 14, 2012 in the District Court of Delaware. The suits claim infringement of U.S. Patent Nos. 6,294,197 ("Solid Oral Dosage Forms of Valsartan," issued September 25, 2001) and 8,101,599 ("Pharmaceutical Composition Containing Anti-Hypertensive Agents," issued January 24, 2012) following a Paragraph IV certification as part of defendants' filing of an ANDA to manufacture a generic version of Novartis's EXFORGE HCT (amlodipine, valsartan, and hydrochlorothiazide).
ALOXI (palonosetron hydrochloride) Helsinn	Prevention of Nausea & Vomiting Associated with Moderately to Highly Emetogenic Cancer Chemotherapy; Prevention of Post-op Nausea & Vomiting	Helsinn filed a patent infringement lawsuit against Dr. Reddy's Laboratories on May 11, 2012 in the District Court of New Jersey. The suit claims infringement of U.S. Patent No. 7,947,724 ("Liquid Pharmaceutical Formulations of Palonosetron," issued May 24, 2011) following a Paragraph IV certification as part of Dr. Reddy's filing of an NDA (under § 505(b)(2) of the Food, Drug and Cosmetic Act) to manufacture a generic version of Helsinn's ALOXI (palonosetron hydrochloride intravenous solution).

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product shortages/recalls/withdrawals/discontinuations

TRADE NAME (generic name) Manufacturer(s)	Therapeutic Category	Strength(s) & Dosage Form(s)	Type	Description/Comments
THAM (tromethamine) Hospira	Minerals & Electrolytes	0.3 M; 500 mL bottle (NDC 0409-1593-04)	SHORTAGE	Shortage due to manufacturing delay. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm?source=govdelivery#tromethamine
DDAVP Rhinal Tube (desmopressin Intranasal) Sanofi-Aventis	Endocrine & Metabolic Agents – Misc.	0.1 mg/mL; 2.5 mL Bottle (NDC 00075-2450-01)	SHORTAGE	Shortage due to manufacturing issue. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm?source=govdelivery#desmopressini
(hydromorphone hydrochloride) Hospira	Analgesics and Anesthetics	1 mg/mL; 1 mL fill in 2.5 mL Carpuject, (NDC 0409-1283-31)	RECALL	Voluntary user level recall of one lot (07547LL; expiration date July 1, 2013) initiated due to two reported complaints of a single Carpuject containing more than the 1 mL labeled fill volume. The affected lot was distributed in September – October 2011. See http://www.fda.gov/Safety/Recalls/ucm303942.htm?source=govdelivery
(potassium chloride Injection) APP; Hospira	Minerals & Electrolytes	2 mEq/mL, 5 mL 10 mL, 15 mL, 20 mL, 30 mL, vials; 250 mL bottles	SHORTAGE	Shortage due to manufacturing delays and increased demand. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm?source=govdelivery#pchloride
(digoxin injection) Sandoz	Cardiac Glycosides	0.25 mg/mL, 2 mL	DISCONTINUATION	Sandoz discontinued manufacturing in March 2011. Sandoz is no longer distributing with no plans for re-introduction. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#digoxindis
(naltrexone) Sandoz	Antidotes	50 mg tablets	DISCOTINUATION	Product is discontinued. Sandoz is no longer distributing with no plans for re-introduction. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#naltrexonedis
(calcitriol injection) West-Ward	Metabolic Modifiers	1 mcg/mL	DISCONTINUATION	West-Ward no longer distributes Calcitriol 1 mcg/mL Injection. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#calcitriol
(ondansetron Injection) West-Ward	Antiemetics	32 mg/50 mL premixed bags	DISCONTINUATION	West-Ward no longer distributes Ondansetron premixed bags. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#ondansetron
REFLUDAN (lepirudin (rDNA) for Injection) Baxter	Anticoagulants	50 mg powder for injection	DISCONTINUATION	Baxter Healthcare Corporation has made a decision to discontinue REFLUDAN for Injection. No further product will be distributed from Bayer after May 31, 2012. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#refludan
(sodium lactate injection) Hospira; Baxter	Minerals & Electrolytes	5 mEq/mL, 10 mL; 167 mEq/mL, 1000 mL	SHORTAGE	Shortage due to manufacturing delays. Baxter has discontinued its 167 mEq/mL, 1000 mL product. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm?source=govdelivery#sodiuml
ELSPAR (asparaginase injection) Lundbeck	Antineoplastics & Adjunctive Therapies	10,000 IU/vial	SHORTAGE	Shortage due to manufacturing delays. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm?source=govdelivery#asparaginase
(dextrose injection, USP) Amphastar	Nutrients	50%, 50 mL Luer-Jet Prefilled Syringe	SHORTAGE	Shortage due to increased demand. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm?source=govdelivery#dextrose

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TRADE NAME (generic name) Manufacturer(s)	Therapeutic Category	Strength(s) & Dosage Form(s)	Type	Description/Comments
COGNEX (tacrine hydrochloride) Shionogi	Antidementia Agents	10 mg & 20 mg capsules	DISCONTINUATION	Shionogi has made a business decision to discontinue COGNEX. There is no remaining inventory within Shionogi, Inc. distribution network. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#cognex
CYANIDE ANTIDOTE KIT (sodium nitrite; sodium thiosulfate; amyl nitrite) Akorn	Antidotes	30 mg/1 mL; 12.5 g/50 mL; 0.3 mL/1 ampule	DISCONTINUATION	Akorn is discontinuing the manufacture of this product and the components for use in this product. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#cyanide
(ondansetron Injection) Apotex	Antiemetics	2 mg/mL 2 mL vials, package of 5; 20 mL multiple dose vial	DISCONTINUATION	Apotex has discontinued the manufacturing of Ondansetron Injection. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#ondansetron2
LUVERIS (lutropin alfa for injection) EMD Serono	Fertility Regulators	75 unit injection	DISCONTINUATION	Business decision to discontinue. See http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050794.htm?source=govdelivery#luveris

guideline update

Topic	Reference/Link
Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association.	*Stroke* published 3 May 2012, 10.1161/STR.0b013e3182587839 http://stroke.ahajournals.org/cgi/content/abstract/STR.0b013e3182587839v1
American College of Rheumatology Guidelines for Screening, Treatment, and Management of Lupus Nephritis.	*Arthritis Care & Research*. Article first published online: 3 MAY 2012 http://onlinelibrary.wiley.com/doi/10.1002/acr.21664/abstract
European Guidelines on cardiovascular disease prevention in clinical practice (version 2012).	http://eurheartj.oxfordjournals.org/content/early/2012/05/02/eurheartj.ehs092.full.pdf+html
ACCF/AHA/AMA-PCPI 2011 Performance Measures for Adults With Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures and the American Medical Association–Physician Consortium for Performance Improvement.	*J Am Coll Cardiol* 2012;59 1812-1832 http://content.onlinejacc.org/cgi/content/full/59/20/1812 *Circulation* 2012;125 2382-2401 http://circ.ahajournals.org/cgi/content/extract/125/19/2382
NCCN has published updates to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Head and Neck Cancers. These NCCN Guidelines are currently available as Version 1.2012.	For the complete updated versions of the NCCN Guidelines and the NCCN Compendium, visit http://www.nccn.org.
ACCF 2012 Health Policy Statement on Patient-Centered Care in Cardiovascular Medicine.	*J Am Coll Cardiol* published 14 May 2012, 10.1016/j.jacc.2012.03.016 http://content.onlinejacc.org/cgi/content/full/j.jacc.2012.03.016v1
Periodontal Disease and Atherosclerotic Vascular Disease: Does the Evidence Support an Independent Association? A Scientific Statement From the American Heart Association.	*Circulation* 2012;125 2520-2544 http://circ.ahajournals.org/cgi/content/abstract/125/20/2520
Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement.	*Ann Intern Med* published 21 May 2012, 10.1059/0003-4819-157-2-201207170-00459 http://www.annals.org/cgi/content/abstract/0003-4819-157-2-201207170-00459v1
Executive Summary: 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections.	*Clin Infect Dis.* (2012) 54 (12): 1679-1684. doi: 10.1093/cid/cis460 http://cid.oxfordjournals.org/content/54/12/1679.full

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Topic	Reference/Link
Menopausal Hormone Therapy for the Primary Prevention of Chronic Conditions: A Systematic Review to Update the U.S. Preventive Services Task Force Recommendations.	*Ann Intern Med* published 28 May 2012, 10.1059/0003-4819-157-2-201207170-00466 http://www.annals.org/cgi/content/abstract/0003-4819-157-2-201207170-00466v1
Prevention of Falls in Community-Dwelling Older Adults: U.S. Preventive Services Task Force Recommendation Statement.	*Ann Intern Med* published 28 May 2012, 10.1059/0003-4819-157-3-201208070-00462 http://www.annals.org/cgi/content/abstract/0003-4819-157-3-201208070-00462v1
Consumer Reports Health Best Buy Drugs - Evaluating Prescription Drugs Used to Treat: Attention Deficit Hyperactivity Disorder (ADHD) - Comparing Effectiveness, Safety, and Price – Newly Updated	http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/ADHDFinal.pdf (full report) http://www.consumerreports.org/health/resources/pdf/best-buy-drugs/2pager_ADHD.pdf (summary)
Genetics and Cardiovascular Disease: A Policy Statement From the American Heart Association.	*Circulation* published 29 May 2012, 10.1161/CIR.0b013e31825b07f8 http://circ.ahajournals.org/cgi/reprint/CIR.0b013e31825b07f8v1
Treatment of Maladaptive Aggression in Youth: CERT Guidelines.	*Pediatrics* Published online May 28, 2012 Part I - Engagement, Assessment, and Management: http://pediatrics.aappublications.org/content/early/2012/05/23/peds.2010-1360.abstract Part II - Treatments and Ongoing Management: http://pediatrics.aappublications.org/content/early/2012/05/23/peds.2010-1361.abstract
Inclusion of Stroke in Cardiovascular Risk Prediction Instruments: A Statement for Healthcare Professionals From the American Heart Association/American Stroke.	*Stroke*. Published online before print May 24, 2012, http://stroke.ahajournals.org/content/early/2012/05/24/STR.0b013e31825bcdac.full.pdf+html

Definitions and resources used for RxHighlights available at https://cic.informedrx.com/wps/portal/irxcic/Login