Current FDA-Related Drug Information

Approvals, Submission, and Important Labeling Changes for US Marketed Pharmaceuticals

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This monthly feature will help readers keep current on new drugs, new indications, dosage forms, and safety-related changes in labeling or use. Efforts have been made to ensure the accuracy of this information; however, if there are any questions, please let me know at danial.baker@wsu.edu.

Table 1. New drugs approved by the US Food and Drug Administration (FDA): February 18, 2014 through March 15, 2014

Droxidopa – Northera (Chelsea Therapeutics)	
<i>Comparative agents:</i>	Norepinephrine
<i>Indication:</i>	Treatment of neurogenic orthostatic hypotension
<i>Mechanism of action:</i>	Synthetic amino acid analog that is metabolized to norepinephrine by dopa-decarboxylase. The increased levels of norepinephrine produce increase peripheral arterial and venous vasoconstriction.
<i>Common adverse effects:</i>	Headache, dizziness, nausea, hypertension, and fatigue
<i>Dosage form & strength:</i>	Capsules; 100 mg, 200 mg, and 300 mg
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/203202lbl.pdf
High-molecular-weight hyaluronan – Monovisc (Anika Therapeutics)	
<i>Comparative agents:</i>	Hyaluronic acid
<i>Indication:</i>	Treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy or simple analgesics (eg, acetaminophen)
<i>Mechanism of action:</i>	Synovial fluid supplement
<i>Common adverse effects:</i>	Arthralgia, joint swelling, and injection site pain
<i>Dosage form & strength:</i>	Injection; single-use 5 mL syringe
<i>Product labeling:</i>	http://www.accessdata.fda.gov/cdrh_docs/pdf9/p090031c.pdf

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Metreleptin – Myalept (AstraZeneca)	
<i>Comparative agents:</i>	None
<i>Indication:</i>	Treat the complications of leptin deficiency, in addition to diet, in patients with congenital generalized or acquired generalized lipodystrophy
<i>Mechanism of action:</i>	Binding to and activating the human leptin receptor (ObR), which belongs to the Class I cytokine family of receptors that signals through the JAK/STAT transduction pathway; also appears to increase insulin sensitivity and reduce food intake
<i>Common adverse effects:</i>	Headache, hypoglycemia, decreased weight, and abdominal pain
<i>Dosage form & strength:</i>	Injection; 11.3 mg/vial
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125390s000lbl.pdf
Testosterone – Aveed (Endo International)	
<i>Comparative agents:</i>	Testosterone injectable products
<i>Indication:</i>	Adult males for conditions associated with a deficiency or absence of endogenous testosterone (eg, primary hypogonadism [congenital or acquired] and hypogonadotropic hypogonadism [congenital or acquired])
<i>Mechanism of action:</i>	Testosterone replacement therapy
<i>Common adverse effects:</i>	Acne, injection site pain, prostatic specific antigen (PSA) increased, estradiol increased, hypogonadism, fatigue, irritability, hemoglobin increased, insomnia, and mood swings
<i>Dosage form & strength:</i>	Injection; 750 mg/3 mL
<i>Product labeling:</i>	http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022219s000lbl.pdf

Table 2. New dosage forms and indications approved by the FDA: February 18, 2014 through March 15, 2014

Generic name	Brand name (Company)	Indication and comments
New dosage forms/ strength/route of administration		
Exenatide	Bydureon (AstraZeneca)	A 2 mg prefilled, single-use pen injector
New indications		
Ivacaftor	Kalydeco (Vertex Pharmaceuticals)	Approved for use in people with cystic fibrosis with the following nine mutations: G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, and G1349D

Table 3. Agents pending FDA approval: February 18, 2014 through March 15, 2014

Generic name	Brand name (Company)	Indication and comments
Complete response letter: more information required		
Empagliflozin	(Boehringer Ingelheim Pharmaceuticals & Eli Lilly and Company)	Deficiencies in the manufacturing facilities need to be addressed.
Recommended for NON-approval by an FDA advisory panel		
Epinephrine	<i>Primatene HFA Inhaler</i> (Armstrong Pharmaceuticals)	Advisory panel voted against (18-6-1) approval as an over-the-counter (OTC) treatment for mild symptoms of intermittent asthma for people aged 12 and over. The vote was favorable for efficacy (14-10-1) and against its safety as an OTC agent (7-17-1).

Table 4. Significant labeling changes or “Dear Health Professional” letters related to safety^a

Generic name Brand name (Company)	Warning
Doripenem <i>Doribax</i> (Shionogi Inc.)	Doripenem is effective for its approved indications for the treatment of complicated intra-abdominal infections and complicated urinary tract infections, including kidney infections (pyelonephritis). It is not approved for the treatment of any type of pneumonia. Compared to imipenem and cilastatin for injection, the use of doripenem in the treatment of pneumonia using ventilators is associated with an increased risk of death and lower clinical cure rates. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm388328.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

^aPractitioners are encouraged to check the Food and Drug Administration's MEDWATCH Web site (<http://www.fda.gov/medwatch/safety.htm>) for updated information.