New Drug Approvals

Cannabidiol (Oral Solution)
Company: GW Pharmaceuticals plc
Date of Approval: June 25, 2018

Epidiolex (cannabidiol) is a prescription pharmaceutical formulation of highly-purified, marijuana plant-derived cannabidiol (CBD) for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients two years of age or older.

Desmopressin Acetate (Sublingual Tablets)
Company: Ferring Pharmaceuticals Inc.
Date of Approval: June 21, 2018

Nocdurna (desmopressin acetate) is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults.

Moxidectin Tablets
Company: Medicines Development for Global Health
Date of Approval: June 13, 2018

Moxidectin is a macrocyclic lactone anthelmintic medicine indicated for the treatment of river blindness (onchocerciasis) in patients aged 12 years and older.

Pegfilgrastim-jmdb (Injection)
Company: Mylan N.V.
Date of Approval: June 4, 2018

Fulphila (pegfilgrastim-jmbd) is a leukocyte growth factor biosimilar to Neulasta (pegfilgrastim) indicated to reduce the duration of febrile neutropenia in patients treated with chemotherapy.

Baricitinib (Tablets)
Company: Eli Lilly and Company
Date of Approval: May 31, 2018

Olumiant (baricitinib) is a Janus kinase (JAK) inhibitor for the treatment of rheumatoid arthritis.

Amlodipine and Celecoxib (Tablets - formerly KIT-302)
Company: Kitov Pharma Ltd.
Date of Approval: May 31, 2018

Consensi (amlodipine and celecoxib) is a calcium channel blocker and nonsteroidal anti-inflammatory drug combination for the treatment of both hypertension and pain associated with osteoarthritis.

Estradiol (Vaginal Inserts)
Company: TherapeuticsMD, Inc.
Date of Approval: May 29, 2018

Imvexxy (estradiol) is a bio-identical 17β-estradiol vaginal insert for the treatment of dyspareunia (vaginal pain during sexual intercourse) due to menopause.

Pegvaliase-pqpz (Injection)
Company: BioMarin Pharmaceutical Inc.
Date of Approval: May 24, 2018

Palynziq (pegvaliase-pqpz) is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria.

Abiraterone Acetate (Tablets)
Company: Sun Pharmaceutical Industries Inc.
Date of Approval: May 22, 2018

Yonsa (abiraterone acetate) is an ultramicrosize formulation of the oral CYP17 inhibitor abiraterone acetate (approved as Zytiga) used in combination with methylprednisolone for the treatment of metastatic castration-resistant prostate cancer.

Avatrombopag (Tablets)
Company: Dova Pharmaceuticals, Inc.
Date of Approval: May 21, 2018

Doptelet (avatrombopag) is a second generation, orally administered thrombopoietin receptor agonist (TPO-RA) indicated for the treatment of thrombocytopenia in patients with chronic liver

disease who are scheduled to undergo a medical procedure.

Sodium Zirconium Cyclosilicate (Oral Suspension)
Company: AstraZeneca
Date of Approval: May 18, 2018

Lokelma (sodium zirconium cyclosilicate) is a potassium binder indicated for the treatment of hyperkalemia in adults.

Erenumab-Aooe (Injection)
Company: Amgen Inc.
Date of Approval: May 17, 2018

Aimovig (erenumab-aooe) is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of migraine.

lofexidine Hydrochloride (Tablets)
Company: US WorldMeds
Date of Approval: May 16, 2018

Lucemyra (lofexidine hydrochloride) is a selective α–2-adrenergic receptor agonist indicated for reducing the severity of withdrawal symptoms in patients experiencing opioid withdrawal.

Epoetin Alfa-Epbx (Injection)
Company: Hospira, Inc.
Date of Approval: May 15, 2018

Retacrit (epoetin alfa-epbx) is an erythropoiesis-stimulating agent (ESA) biosimilar to Epogen/Procrit (epoetin alfa) indicated for treatment of anemia caused by chronic kidney disease, chemotherapy, or use of zidovudine in patients with HIV infection. Retacrit is also approved for use before and after surgery to reduce the chance that red blood cell transfusions will be needed because of blood loss during surgery.

Polyethylene glycol 3350 with electrolytes (Oral Solution)
Company: Salix Pharmaceuticals, Inc.
Date of Approval: May 4, 2018

Plenvu (polyethylene glycol 3350, sodium ascorbate, sodium sulfate, ascorbic acid, sodium chloride and potassium chloride) is a lower-volume, polyethylene glycol based osmotic laxative indicated for cleansing of the colon (bowel preparation) prior to colonoscopy.

Coagulation factor Xa (recombinant), inactivated-zhzo
Company: Portola Pharmaceuticals, Inc.
Date of Approval: May 3, 2018

Andexxa (coagulation factor Xa (recombinant), inactivated-zhzo) is a recombinant modified human Factor Xa (FXa) protein indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Tolvaptan (Tablets)
Company: Otsuka Pharmaceutical Co., Ltd
Date of Approval: April 23, 2018

Jynarque (tolvaptan) is a selective vasopressin V_2-receptor antagonist indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

Fosnetupitant and palonosetron
Company: Helsinn Healthcare SA
Date of Approval: April 19, 2018

Akynzeo for Injection (fosnetupitant and palonosetron) is a substance P/neurokinin-1 (NK-1) receptor antagonist and serotonin-3 (5-HT3) receptor antagonist combination indicated for use with dexamethasone for the prevention of chemotherapy-induced nausea and vomiting (CINV).

Burosumab-twza (Injection)
Company: Ultragenyx Pharmaceutical Inc.
Date of Approval: April 17, 2018

Crysvita (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody for the treatment of x-linked hypophosphatemia (XLH).

Fostamatinib (Tablets)
Company: Rigel Pharmaceuticals, Inc.
Date of Approval: April 17, 2018

Tavalisse (fostamatinib) is an oral spleen tyrosine kinase (SYK) inhibitor for the treatment of patients with chronic immune thrombocytopenia (ITP).

Ibalizumab-uiyk (Injection)
Date of Approval: March 6, 2018
Company: TaiMed Biologics USA Corp.

Trogarzo (ibalizumab-uiyk) is a CD4-directed post-attachment HIV-1 inhibitor for the treatment of multidrug resistant human immunodeficiency virus-1 (HIV-1) infection in heavily treatment-experienced adults.

Tildrakizumab-asmn (Injection)
Date of Approval: March 20, 2018
Company: Sun Pharmaceutical Industries Ltd.

Ilumya (tildrakizumab-asmn) is a humanized, anti-IL-23p19 monoclonal antibody for the treatment of moderate-to-severe plaque psoriasis.

Information Collected and complied by:
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Efavirenz, lamivudine and tenofovir disoproxil fumarate (Tablets)
Date of Approval: March 22, 2018
Company: Mylan N.V.

Symfi (efavirenz, lamivudine and tenofovir disoproxil fumarate) is a three-drug combination of a non-nucleoside reverse transcriptase inhibitor (efavirenz), and two nucleo(t)side reverse transcriptase inhibitors (lamivudine and tenofovir disoproxil fumarate) indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection.

Source: Drugs.com

New Indications & Dosage form for Existing Drugs

Immune globulin subcutaneous
FDA approves Hizentra (Immune Globulin subcutaneous [Human] 20% Liquid) for the treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP)
New Indication Approved: March 15, 2018

Brentuximab vedotin
FDA expands approval of adcetris (brentuximab vedotin) for first-line treatment of stage III or IV classical hodgkin lymphoma in combination with chemotherapy.
New Indication Approved: March 20, 2018

Bevacizumab (Injection)
Avastin (bevacizumab) is a recombinant humanized monoclonal IgG1 antibody for the treatment of colorectal cancer, non-small cell lung cancer, glioblastoma, renal cell carcinoma, cervical cancer, ovarian cancer, fallopian tube cancer, and peritoneal cancer.
New Indication Approved: June 13, 2018

Pembrolizumab (Injection)
Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma.
New Indication Approved: June 13, 2018

Pembrolizumab (Injection)
Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, cervical cancer, and primary mediastinal large B-cell lymphoma.
New Indication Approved: June 12, 2018

Venetoclax (Tablets)
Venclexta (venetoclax) is an oral B-cell lymphoma-2 (BCL-2) inhibitor for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion.
New Indication Approved: June 8, 2018

Rituximab (Injection for Intravenous Use)
Rituxan (rituximab) is a CD20-directed cytolytic antibody indicated for the treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, Wegener's granulomatosus, microscopic polyangiitis, and pemphigus vulgaris.
New Indication Approved: June 7, 2018

Tofacitinib (Tablets)
Xeljanz (tofacitinib) is an oral Janus kinase (JAK) inhibitor for the treatment of adult patients with moderately to severely active rheumatoid arthritis, active psoriatic arthritis, and moderately to severely active ulcerative colitis.
New Indication Approved: May 30, 2018

Certolizumab pegol (Injection)
Cimzia (certolizumab) is a PEGylated anti-TNF (tumor necrosis factor) biologic therapy for the treatment of Crohn’s disease, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.
New Indication Approved: May 25, 2018

Denosumab (Injection)
Prolia is a RANK ligand (RANKL) inhibitor indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, for the treatment of bone loss in patients with prostate or breast cancer undergoing hormone ablation therapy, as a treatment to increase bone mass in men with osteoporosis at high risk for fracture, and for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture.
New Indication Approved: May 18, 2018

Ixekizumab (Injection)
Taltz (ixekizumab) is a humanized interleukin-17A antagonist indicated for the treatment of plaque psoriasis and psoriatic arthritis.
New Indication Approved: May 17, 2018

Tocilizumab (Injection)
Actemra (tocilizumab) is a humanized interleukin-6 (IL-6) receptor-inhibiting monoclonal antibody for the treatment of rheumatoid arthritis; systemic juvenile idiopathic arthritis (SJIA); polyarticular juvenile idiopathic arthritis (PJIA); giant cell arteritis; and CAR T cell-induced severe or life-threatening cytokine release syndrome.
New Dosage Regimen: May 11, 2018

Daratumumab (Injection)
Darzalex (daratumumab) is a human anti-CD38 monoclonal antibody indicated for the treatment of patients with multiple myeloma.
New Indication Approved: May 7, 2018

Tisagenlecleucel (Suspension for Intravenous Infusion)
Kymriah (tisagenlecleucel) is a chimeric antigen receptor T cell (CAR-T) therapy for use in patients with relapsed or refractory (r/r) B-cell acute lymphoblastic leukemia (ALL) and patients with relapsed or refractory (r/r) large B-cell lymphoma.
New Indication Approved: May 1, 2018

Mirabegron (Extended Release Tablets)
Myrbetriq (mirabegron) is a β-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and urinary frequency.
New Indication Approved: April 27, 2018

Osimertinib (Tablets)
Tagrisso (osimertinib) is a tyrosine kinase inhibitor (TKI) of epidermal growth factor receptor (EGFR) indicated for the treatment of patients with metastatic EGFR T790M mutation-positive non-small cell lung cancer.
New Indication Approved: April 18, 2018

Nivolumab (Injection)
Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer and hepatocellular carcinoma.
New Indication Approved: April 16, 2018

Everolimus (Tablets)
Afinitor (everolimus) is an oral once-daily inhibitor of mTOR indicated for the treatment of patients with advanced HR+, HER2- breast cancer; progressive neuroendocrine tumors of pancreatic origin (PNET); progressive neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin; advanced renal cell carcinoma; and subependymal giant cell astrocytoma (SEGA) and renal angiomyolipomas associated with tuberous sclerosis.
New Indication Approved: April 10, 2018

Rucaparib (Tablets)
Rubraca (rucaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies; and for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
New Indication Approved: April 6, 2018

Bupivacaine liposome (Injectable Suspension)
Exparel (bupivacaine liposome injectable suspension) is a long-acting non-opioid local analgesic for postsurgical local analgesia, and for use as a nerve block (interscalene brachial plexus block) to provide pain relief following shoulder surgeries.
New Indication Approved: April 6, 2018

Blinatumomab (Injection)
Blincyto (blinatumomab) is a bispecific CD19-directed CD3 T-cell engager indicated for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL), and minimal residual disease (MRD)-positive B-cell precursor ALL.
New Indication Approved: March 29, 2018

Blinatumomab
FDA expands approval of blincyto (blinatumomab) to treat minimal residual disease-positive B-Cell precursor acute lymphoblastic leukemia
New Indication Approved: March 29, 2018

Otiprio (ciprofloxacin)
Treatment for: Tympanostomy Tube Placement Surgery; Acute Otitis Externa
New Indication Approved: March 2, 2018

Source: Drugs.com

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Current Pharma News

Bowel Cancer: Low-calorie soft drinks could reduce recurrence

Published: July 20, 2018

By Catharine Paddock PhD

Consuming artificially sweetened soft drinks such as diet colas may be linked to a significantly lower risk of cancer return or death in patients with stage 3 colorectal cancers.

Are essential oils safe for babies?

Last reviewed Friday 20 July 2018

By Amanda Barrell

Reviewed by Carissa Stephens, RN, CCRN, CPN

There is some evidence for the benefits of essential oils, but very little research on how these oils may affect babies. It is crucial to note that the American Association of Naturopathic Physicians do not recommend using essential oils at all on babies younger than 3 months.

How long does nicotine stay in your system?

Last reviewed Thursday 19 July 2018

By Danielle Dresden

Reviewed by Alan Carter, PharmD

When people use tobacco products, some of the nicotine stays in their system after they quit smoking. Medical tests can detect nicotine in people's urine, blood, saliva, hair and nails. Nicotine is the addictive substance in tobacco, cigarettes and vapes or e-cigarettes.

When someone smokes a cigarette, their body absorbs up to 90 percent of the nicotine. Traces of nicotine will linger long after individuals no longer feel the effects. After smoking a cigarette, nicotine and its by-products stay in a person’s urine and saliva for 4 days and blood for up to 10 days.

Eating dinner earlier could reduce cancer risk

Published Thursday 19 July 2018

By Tim Newman

According to a study that was conducted at the Barcelona Institute for Global Health in Spain, eating your final meal of the day too late can increase the risk of developing cancer.

The relationship between food and cancer has been investigated to a great deal. For instance, regularly eating fresh vegetables has been shown to reduce cancer risk. Conversely, regularly eating red meat increases the risk of certain cancers.

A recent study investigated potential links between meal timing and two common types of cancer: prostate cancer and breast cancer.

Source: medicalnewstoday.com

Non-dairy beverages like soy and almond milk may not be 'milk,' FDA suggests

By Lindsey Ellefson, CNN

Updated: July 19, 2018

*(CNN)*Got milk? If you're buying "milk" made with non-dairy products like almonds or oats, the US Food and Drug Administration isn't so sure you do.

During a the Politico Pro Summit on Tuesday, FDA Commissioner Dr. Scott Gottlieb questioned whether the "standards of identity" applied to milk in the United States are being enforced correctly.

The FDA describes milk as "the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows." That definition doesn't leave room for vegan alternatives to call themselves "milk," though a number of products on the market do.

Non-dairy milks, including soy, almond, rice and coconut milk are juices from nuts, seeds, grains and legumes that may be fortified with vitamins and minerals to deliver the equivalent nutrient profile and sometimes taste and consistency of cow's milk.

Source: cnn.com/health

The risk of having a heart attack while pregnant, giving birth, or during the two months after delivery, continues to increase for American women, a new study finds.

As published online July 18 in the *Mayo Clinic Proceedings*, the study, led by NYU School of Medicine researchers, found that the risk of suffering a heart attack among pregnant women rose 25 percent from 2002 to 2014.

The researchers suggest that the trend among many women to have children later in life is one possible reason for the increase, as heart attack risk rises with age overall, and especially during pregnancy. More women, they say, are also obese and/or have diabetes, key risk factors for heart attack. Another factor that may explain the rising numbers is that myocardial infarcts, the technical name for heart attacks, are easier to detect than a decade ago, as tests for early protein markers of related heart cell damage have improved and become more widely available.

Source: sciencedaily.com

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Herbal and Alternative Medicine News

Green tea molecule could prevent heart attacks
Date: May 31, 2018
Source: British Heart Foundation
Scientists have discovered that a compound found in green tea, currently being studied for its ability to reduce amyloid plaques in the brain in Alzheimer's disease, also breaks up and dissolves potentially dangerous protein plaques found in the blood vessels.

Nanoparticles derived from tea leaves destroy lung cancer cells: Quantum dots have great potential
Date: May 21, 2018
Source: Swansea University
Nanoparticles derived from tea leaves inhibit the growth of lung cancer cells, destroying up to 80 percent of them, new research has shown. The team made the discovery while they were testing out a new method of producing a type of nanoparticle called quantum dots. These are tiny particles which measure less than 10 nanometers. A human hair is 40,000 nanometers thick.

Reishi mushroom powder is an effective treatment for mouth ulcers
Published Date: 07/17/2018, By Edsel Cook
The medicinal mushroom known as “Reishi ” in Japan was the subject of a recent Chinese study on alternative treatments for recurrent oral ulceration (ROU). The results showed that freeze-dried reishi mushroom powder provided effective treatment for the most prevalent mouth ulcer disease in the world. ROU is considered an autoimmune disease. It is a frequent complication for acquired immune deficiency syndrome (AIDS) and other diseases that undermine the immune system.

Asafoetida, a plant used in traditional folk medicines, found to show antitumor effects on breast cancer
Published Date: 07/17/2018, By Ralph Flores

Information Collected and complied by:
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Plants and herbs that have long been used in folk medicine may very well hold the key to treating modern-day diseases. In a study published in the *Journal of Ayurveda and Integrative Medicine*, researchers found that asafoetida, a plant used in traditional food and medicine, could potentially have anti-tumor and anti-metastasis effect against breast cancer. The study, led by researchers from *Shahid Sadoughi University of Medical Sciences* and *Ahvaz Jundishapur University of Medical Sciences* in Iran, looked at the effect of an oleo gum resin from asafoetida in mice induced with breast cancer.

Herbal plants found to treat tuberculosis naturally
Published Date: 07/17/2018, By Rhonda Johansson
A major issue facing the medical community today is the rise of multidrug-resistant tuberculosis, which hampers current efforts to end the deadly disease globally. The *World Health Organization* (WHO) estimates that while the incidences of tuberculosis have been decreasing by around two percent each year, all effort must be made in exploring every option to treat it.

This includes validating well-known traditional ethnomedicines. It was with this goal that researchers analyzed the extracts of crepe jasmine (*Tabernaemontana coronaria*), lemongrass (*Cymbopogon citratus*) and crepe ginger (*Costus speciosus*). These plant materials have been traditionally used as remedies for various symptoms of tuberculosis.

Researchers evaluated the three plant extracts for their anti-tuberculosis activity. Part of their analysis included assessing which phytochemical compounds were the most active in influencing the growth kinetics and cellular integrity of a tubercle organism.

Source: alternativemedicine.news