First-Time Generic Approvals

Tofacitinib
Brand name: Xeljanz, Xeljanz XR
Dosage forms: oral solution (1 mg/mL); oral tablet (10 mg; 5 mg); oral tablet, extended release (11 mg; 22 mg)
Drugs class: Antirheumatics
Tofacitinib is used to treat moderate to severe rheumatoid arthritis or active psoriatic arthritis in adults who have tried methotrexate or other medications without successful treatment of symptoms. Tofacitinib is sometimes given in combination with methotrexate or other arthritis medicines.

Lopinavir and Ritonavir
Brand name: Kaletra
Dosage forms: oral liquid (400 mg-100 mg/5 mL); oral tablet (100 mg-25 mg; 200 mg-50 mg)
Drugs class: Protease inhibitors
Lopinavir and ritonavir is a combination antiviral medicine used to treat human immunodeficiency virus (HIV), the virus that can cause acquired immunodeficiency syndrome (AIDS). Lopinavir and ritonavir is not a cure for HIV or AIDS.

Etravirine
Brand name: Intelence
Dosage forms: Oral tablet (100 mg; 200 mg; 25 mg)
Drugs class: NNRTIs
Etravirine is an antiviral medicine that is used with other medicines to treat human immunodeficiency virus (HIV). HIV causes the acquired immunodeficiency syndrome (AIDS). Etravirine is not a cure for HIV or AIDS.

Formoterol (inhalation)
Brand name: Perforomist, Foradil Aerolizer
Dosage forms: Inhalation Solution (20 mcg/2 mL)
Drugs class: Adrenergic bronchodilators
Formoterol inhalation is used to control the symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Arformoterol Inhalation
Brand name: Brovana
Dosage forms: Inhalation Solution (15 mcg/2 mL)
Drugs class: Adrenergic bronchodilators
Arformoterol inhalation is used to help control the symptoms of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Enzalutamide
Brand name: Xtandi
Dosage forms: Oral Capsule (40 mg); oral tablet (40 mg; 80 mg)
Drugs class: Antiandrogens, Hormones / antineoplastics
Enzalutamide is a prescription medicine used to treat prostate cancer in men who have received surgery or hormone therapy to lower testosterone.

Lenalidomide
Brand name: Revlimid
Dosage forms: Oral Capsule (10 mg; 15 mg; 2.5 mg; 20 mg; 25 mg; 5 mg)
Drugs class: Miscellaneous antineoplastics, Other immunosuppressants
Lenalidomide is used to treat multiple myeloma (bone marrow cancer), either in combination with another medicine or after stem cell transplant.

Deoxycholic Acid
Brand name: Kybella
Dosage forms: Subcutaneous Solution (10 mg/mL)
Drugs class: Miscellaneous uncategorized agents
Deoxycholic acid is a manmade form of a substance your body makes that helps to absorb fats. Deoxycholic acid works by destroying fat cells where it is injected into the body.

Macitentan
Brand name: Opxsmit
Dosage forms: Oral Tablet (10 mg)
Drugs class: Agents for pulmonary hypertension
Macitentan lowers blood pressure in your lungs, helping your heart pump blood more efficiently. Macitentan is used to treat pulmonary arterial hypertension (PAH). It improves your ability to exercise and prevents your condition from getting worse.

**Tiopronin**

**Brand name:** Thiola, Thiola EC  
**Dosage forms:** oral delayed release tablet (100 mg; 300 mg); oral tablet (100 mg)

**Drug class:** Miscellaneous genitourinary tract agents  
Tiopronin is used together with diet, fluids, and other medicines to help prevent kidney stones in adults and children weighing at least 44 pounds (20 kilograms).

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