Brand Name	Generic Name	Indications	Route of Administration	Date of Action	Action
J&J COVID-19 Vaccine	N/A	COVID-19 Prevention	Intramuscular	4/13/2021	On April 13, 2021, the CDC and FDA recommended a **pause in the use of the Johnson & Johnson (J&J) coronavirus vaccine** out of an abundance of caution due to six reports of blood clots.
N/A	bamlanivimab	Mild-Moderate COVID-19 in select pediatric and adult patients	Intravenous	4/16/2021	On April 16, 2021, the FDA **revoked the emergency use authorization** (EUA) for Eli Lilly's bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and certain pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 vial testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. In the U.S., bamlanivimab alone should no longer be administered. However, sites of care should not dispose of bamlanivimab supply; instead, they should order etesevimab to pair with it. Eli Lilly requested the FDA revoke the EUA for bamlanivimab 700 mg alone. Lilly made this request due to the evolving variant landscape in the U.S. and the full availability of bamlanivimab/etesevimab together. Recent data from the U.S. Centers for Disease Control and Prevention's (CDC) national genomic surveillance program show an increased frequency of SARS-CoV-2 variants that are expected to be resistant to bamlanivimab administered alone.
J&J COVID-19 Vaccine	N/A	COVID-19 Prevention	Intramuscular	4/23/2021	On April 23, 2021, the CDC's Advisory Committee on Immunization Practices (ACIP) convened an emergency meeting to reassess the risk benefit profile of the Johnson & Johnson (J&J) coronavirus vaccine. After reviewing the current data, hearing from J&J, and deliberating on different options, they **decided to reaffirm their original recommendations for the vaccine for ages and genders.** The recommendation is: — The Janssen (J&J) COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.

Brand Name	Generic Name	Indications	Route of Administration	Date of Action	Action
Ocaliva	Obeticholic Acid	Primary Biliary Cholangitis	Oral	5/26/2021	On May 26, 2021, the FDA announced that a **new Contraindication** will be added to the Ocaliva (obeticholic acid) drug label stating that it **should not be used in primary biliary cholangitis (PBC) patients with advanced cirrhosis**. PBC is a rare, chronic disease affecting the ducts in the liver that carry bile, which helps with digestion. Some PBC patients with cirrhosis who took Ocaliva, especially those with evidence of advanced cirrhosis, developed liver failure, sometimes requiring liver transplant.
Chantix	varenicline	Smoking Cessation	Oral	6/24/2021	On June 24, 2021, multiple media outlets began reporting that Pfizer was suspending distribution of the smoking cessation aid, Chantix (varenicline), due to discovery of impurities that were found in some of the tablets during product testing. **Pfizer identified nitrosamine impurities in at least a few lots of Chantix,** and halted supply "out of an abundance of caution". Neither the FDA nor Pfizer have yet issued a recall notification. Wholesalers are listing Chantix as backordered from the manufacturer with no expected date to resume shipping product.