The FDA's MedWatch program safety labeling changes for boxed warnings are compiled quarterly for drugs and therapeutic biologics where important changes have been made to the safety information. These and other label changes are searchable in the Drug Safety Labeling Changes (SLC) database, where data are available to the public in downloadable and searchable formats. Boxed warnings are ordinarily used to highlight either adverse reactions so serious in proportion to the potential benefit from the drug that it is essential that it be considered in assessing the risks and benefits of using the drug; or serious adverse reactions that can be prevented/reduced in frequency or severity by appropriate use of the drug; or FDA approved the drug with restrictions to ensure safe use because FDA concluded that the drug can be safely used only if distribution or use is restricted. For complete FDA Drug Safety Labeling changes, please visit http://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges.

VIDEX AND VIDEX EC (DIDANOSINE):

Edited boxed warning, January 2018

WARNING: PANCREATITIS, LACTIC ACIDOSIS and HEPATOMEGALY with STEATOSIS

Coadministration of VIDEX or VIDEX EC and stavudine is contraindicated because of increased risk of serious and/or life-threatening events. Suspend treatment if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity occurs.

FERAHEME (FERUMOXYTOL):

Edited boxed warning, February 2018

WARNING: RISK FOR SERIOUS HYPERSENSITIVITY/ANAPHYLAXIS REACTIONS

Fatal and serious hypersensitivity reactions including anaphylaxis have occurred in patients receiving feraheme. Initial symptoms may include hypotension, syncope, unresponsiveness, cardiac/cardiorespiratory arrest.

Only administer feraheme as an intravenous infusion over at least 15 minutes and only when personnel and therapies are immediately available for the treatment of anaphylaxis and other hypersensitivity reactions.

ZYDELIG (IDELALISIB):

Edited boxed warning, January 2018

WARNING: FATAL AND SERIOUS TOXICITIES: HEPATIC, SEVERE DIARRHEA, COLITIS, PNEUMONITIS, INFECTIONS, and INTESTINAL PERFORATION

Fatal and/or serious hepatotoxicity occurred in 16% to 18% of Zydelig-treated patients…

Fatal and/or serious and severe diarrhea or colitis occurred in 14% to 20% of Zydelig-treated patients…

Fatal and/or serious infections occurred in 21% to 48% of Zydelig-treated patients…

AQUAMEPHYTON (PHYTONADIONE):

Edited boxed warning, March 2018

WARNING: HYPERSENSITIVITY REACTIONS WITH INTRAVENOUS AND INTRAMUSCULAR USE

Fatal hypersensitivity reactions, including anaphylaxis, have occurred during and immediately after INTRAVENOUS and INTRAMUSCULAR injection of AquaMEPHYTON. Reactions have occurred despite dilution to avoid rapid infusion and upon first dose. Avoid the intravenous and intramuscular routes of administration unless the subcutaneous route is not feasible and the serious risk is justified.

METHADONE HYDROCHLORIDE, METHADOSE (METHADONE HYDROCHLORIDE):

Edited boxed warning, February 2018

RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Concomitant use with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, is a risk factor for respiratory depression and death.

Reserve concomitant prescribing of benzodiazepines or other CNS depressants for use in patients for whom alternatives to benzodiazepines or other CNS depressants are inadequate.

Follow patients for signs and symptoms of respiratory depression and sedation. If the patient is visibly sedated, evaluate the cause of sedation, and consider delaying or omitting daily methadone dosing.

DOLOPHINE HYDROCHLORIDE (METHADONE HYDROCHLORIDE):

Edited boxed warning, February 2018

RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

Reserve concomitant prescribing of DOLOPHINE Tablets and benzodiazepines or other CNS depressants for use in patients for whom alternatives to benzodiazepines or other CNS depressants are inadequate.

Limit dosages and durations to the minimum required for patients being treated for pain.

Follow patients for signs and symptoms of respiratory depression and sedation. If the patient is visibly sedated, evaluate the cause of sedation, and consider delaying or omitting the daily methadone dose.

PARNATE (TRANYLCYPROMINE SULFATE):

Edited boxed warning, January 2018

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS AND HYPERTENSIVE CRISIS WITH SIGNIFICANT TYRAMINE USE

SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. PARNATE is not approved for use in pediatric patients.

HYPERTENSIVE CRISIS WITH SIGNIFICANT TYRAMINE USE

Excessive consumption of foods or beverages with significant tyramine content or the use of certain drugs with PARNATE or after PARNATE discontinuation can precipitate hypertensive crisis. Monitor blood pressure and allow for medication-free intervals between administration of PARNATE and interacting drugs. Instruct patients to avoid ingestion of foods and beverages with high tyramine content.

OCALIVA (OBETICHOLIC ACID):

New boxed warning/Newly added section, February 2018

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with primary biliary cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.

The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.