New FDA Watch List Flags More Drugs

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The US Food and Drug Administration (FDA) spotted possible safety blips on its radar for 14 drugs or drug classes in the first 3 months of 2017, which put them on the agency's latest watch list.

The watch list, posted last week on the FDA website, reflects potential signals of serious risk or new safety information gathered by the FDA Adverse Event Reporting System (FAERS).

In the case of four drugs or drug classes, the agency already has reached a regulatory resolution. The FDA decided that on the basis of available information, no action was needed right now regarding reports of kidney stones in patients with type 2 diabetes who took sodium-glucose cotransporter-2 (SGLT-2) inhibitors to lower blood glucose levels. It took the same stance on reports of rhabdomyolysis — a breakdown of muscle tissue that can lead to kidney damage — in patients who took methimazole tablets for hyperthyroidism, Graves disease, thyrotoxic crisis, and other disorders.

With two other drugs, the FDA already has revised the labels. In the case of the anticonvulsant medicine levetiracetam (*Keppra*, UCB), the label's section on adverse reactions reported after approval was updated to include the risk for acute kidney injury. The change also applies to the extended-release version of the drug.

The FDA revised the label of two forms of the antibiotic daptomycin (*Cubicin* and *Cubicin RF,* Merck) to warn not about an inherent risk but a medication error that clinicians could commit. The labels now state that each drug is reconstituted from powder differently — a sodium chloride solution for Cubicin and either sterile or bacteriostatic water for injection for Cubicin RF. Differences also extend to how the drugs are stored.

The FDA notes that a drug's appearance on a quarterly FAERS watch list does not mean that the agency has determined a causal relationship between the drug and the adverse event. What it does mean is further study. If the FDA concludes that there is a causal link, it can collect more data to better describe the risk, change the drug's label, order a risk evaluation and mitigation strategy, or pull the product from the market.

Product Name: Trade (Active Ingredient) or Product Class	Potential Signal of a Serious Risk/New Safety Information	Additional Information (as of June 30, 2017)
Alli (orlistat) capsules *Xenical* (orlistat) capsules, for oral use	Orlistat and neuropsychiatric adverse events	FDA is evaluating the need for regulatory action.
Cubicin (daptomycin for injection) for intravenous use	Medication error	The container labels and carton labeling were revised. In addition, the "Dosage and Administration" section of the labeling was

Cubicin RF (daptomycin for injection) for intravenous use		updated to better differentiate the two formulations. Cubicin labeling Cubicin RF labeling
Exjade (deferasirox) tablets, for oral suspension *Jadenu* (deferasirox) tablets, for oral use	Pediatric fever and dehydration	FDA is evaluating the need for regulatory action.
Gonadotropin-releasing hormone agonists Lupron (leuprolide acetate) injection *Lupron* Depot PED (leuprolide acetate for depot suspension), injection, powder, lyophilized, for suspension *Supprelin* LA (histrelin acetate) subcutaneous implant *Synarel* (nafarelin acetate) nasal solution	Musculoskeletal and connective tissue pain and discomfort	FDA is evaluating the need for regulatory action.
Keppra (levetiracetam) tablets, for oral use *Keppra* (levetiracetam) extended-release tablets, for oral use *Keppra* (levetiracetam) oral solution *Keppra* (levetiracetam) injection, for intravenous use	Acute kidney injury and interstitial nephritis	The "Adverse Reactions; Postmarketing Experience" section of the labeling for Keppra and Keppra XR was updated to include acute kidney injury. Keppra XR labeling Keppra labeling (tablets and oral solution) Keppra labeling (injection)
Keytruda (pembrolizumab) for injection, for intravenous	Ocular toxicities, including vision	FDA is evaluating the need for regulatory action.

use	loss and retinal detachment	
*Opdivo (*nivolumab) injection, for intravenous use		
Yervoy (ipilimumab) injection, for intravenous use		
Kybella (deoxycholic acid) injection, for subcutaneous use	Injection site infection and necrosis	FDA is evaluating the need for regulatory action.
Methimazole tablets	Rhabdomyolysis in methimazole	FDA decided that no action is necessary at this time, based on available information.
Neulasta Onpro kit (pegfilgrastim) injection, for subcutaneous use	Device failure	FDA is evaluating the need for regulatory action.
Ofev (nintedanib) capsules, for oral use	Liver dysfunction	FDA is evaluating the need for regulatory action.
SGLT-2 inhibitors	Nephrolithiasis	FDA decided that no action is necessary at this time, based on available information.
*Farxiga (*dapagliflozin) tablets, for oral use		
Glyxambi (empagliflozin and linagliptin) tablets, for oral use		
Invokamet (canagliflozin and metformin hydrochloride) tablets, for oral use		
Invokamet XR (canagliflozin and metformin hydrochloride extended-release) tablets, for oral use		
Invokana (canagliflozin) tablets, for oral use		
Jardiance (empagliflozin) tablets, for oral use		
Synjardy (empagliflozin and metformin hydrochloride) tablets, for oral use		
Synjardy XR (empagliflozin and metformin hydrochloride		

extended-release) tablets, for oral use		
Xigduo XR (dapagliflozin and metformin hydrochloride extended-release) tablets, for oral use		
Stelara (ustekinumab) injection, for subcutaneous use	Interstitial pneumonia	FDA is evaluating the need for regulatory action.
Tanzeum (albiglutide) for injection, for subcutaneous use *Trulicity* (dulaglutide), injection, for subcutaneous use	Serious hypersensitivity reactions	FDA is evaluating the need for regulatory action.
Uloric (febuxostat) tablets, for oral use	Drug reaction with eosinophilia and systemic symptoms	FDA is evaluating the need for regulatory action.

More information about FAERS and its quarterly watch lists are available on the FDA website.

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