FDA approves admelog for diabetes

December 12 2017

(HealthDay)—Admelog (insulin lispro), a short-acting form of insulin, has been approved by the U.S. Food and Drug Administration to treat patients aged 3 years and older with either type of diabetes.

Admelog is the first drug approved as a follow-up product based on an abbreviated new process dubbed 505(b)(2), the agency said Monday in a news release. A new drug approved this way relies on the agency's finding that "a previously approved drug is safe and effective, or on published literature to support the safety and/or effectiveness of the proposed product, if such reliance is scientifically justified," the FDA said. The abbreviated process can reduce "development costs so products can be offered at a lower price to patients," the agency explained.

Admelog was approved under the new process in part due to its similarity to Humalog, the agency said. Admelog itself was evaluated in clinical trials involving about 1,000 patients.

The most common side effects included hypoglycemia, itching, and rash. A less common but more serious adverse reaction could include life-threatening allergic reaction, including anaphylaxis. Admelog should not be used by patients with hypoglycemia, or by those who are hypersensitive to the drug's active ingredient insulin lispro, the agency warned. Patients at risk of hyperkalemia should be monitored carefully while taking Admelog.

Admelog is produced by the French firm Sanofi-Aventis, whose U.S. headquarters is based in Chattanooga, Tenn.

More information: More Information