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FDA approves first generic version of EpiPen

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The FDA has approved several epinephrine auto-injector products under new drug applications to treatanaphylaxis, including EpiPen, Adrenaclick and Auvi-Q.

The U.S. Food and Drug Administration has approved the first generic version of EpiPen and EpiPen Jr (epinephrine) auto-injector for the emergency treatment of allergic reactions, including those that are life-threatening (anaphylaxis), in adults and pediatric patients who weigh more than 33 pounds. Teva Pharmaceuticals USA gained approval to market its generic epinephrine auto-injector in 0.3 mg and 0.15 mg strengths.

“Today’s approval of the first generic version of the most-widely prescribed epinephrine auto-injector in the U.S. is part of our longstanding commitment to advance access to lower cost, safe and effective generic alternatives once patents and other exclusivities no longer prevent approval,” said FDA Commissioner Scott Gottlieb, M.D. “This approval means patients living with severe allergies who require constant access to life-saving epinephrine should have a lower-cost option, as well as another approved product to help protect against potential drug shortages. The path to developing generic drug-device combination products like this one is challenging. We remain committed to doing our part to provide scientific and regulatory clarity for sponsors seeking to develop complex generics, as well as prioritize the approval of medicines with little or no generic competition as part of our overarching effort to remove barriers to generic development and market entry of critically important medicines. Many of these steps were outlined in our Drug Competition Action Plan, announced last year. We’re especially committed to the development of generic copies of complex products. These products can be hard to copy, and therefore sometimes don’t face timely generic competition once patents and exclusivities are no longer a block to approval. We’re advancing new guidance for sponsors to make the development of generic versions of complex products more efficient, and we’re prioritizing review of many complex generic drug applications.”

Life-threatening allergies can include reactions to insect bites or stings, foods, medications, latex or other causes. Anaphylaxis is a medical emergency that affects the whole body and, in some cases, leads to death. Anaphylaxis occurs in approximately one in 50 Americans. People who have had an anaphylaxis episode always face the risk of another one. Because of this risk, they must carry an emergency dose of epinephrine at all times. Many must keep more than one dose at hand.

The EpiPen is intended to automatically inject a dose of epinephrine into a person's thigh to stop an allergic reaction. The FDA has approved several epinephrine auto-injector products under new drug applications to treat anaphylaxis, including EpiPen, Adrenaclick and Auvi-Q. In addition, "authorized generic" versions of EpiPen and Adrenaclick are marketed without the brand names. An authorized generic is made under the brand name's existing new drug application using the same formulation, process and manufacturing facilities that are used by the brand name manufacturer. The labeling or packaging is, however, changed to remove the brand name or other trade dress. In some cases, a company may choose to sell an authorized generic at a lower cost than the brand-name drug product.

Epinephrine auto-injector products are known as "combination products" because they consist of a drug (epinephrine) and a device (the auto-injector). This epinephrine injection (auto-injector) is intended for immediate administration to patients. When given intramuscularly or subcutaneously, it has a rapid onset and short duration of action. Epinephrine works by reducing swelling in the airway and increasing blood flow in the veins.

The most common side effects associated with epinephrine injection are anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache and/or respiratory difficulties. Rare cases of serious skin and soft tissue infections have been reported following use of the drug. In patients with heart disease, use of epinephrine injection may cause chest pain (angina pectoris) or abnormal heart beats (ventricular arrhythmias). Following use of epinephrine injection, patients should seek immediate medical or hospital care. Epinephrine should not be injected into the vein, buttock, fingers, hands or feet. To minimize risk of injection-site injury, movement of the leg should be limited during injection.