

# Free Market Win: FDA Approves Competition In The Allergy EpiPen Space

By ACSH Staff — August 17, 2018



Allergies can be annoying but in some instances they are life threatening. That situation, anaphylaxis, is a medical emergency and occurs in up to two percent of Americans.

If anaphylaxis occurs once it is more likely to happen again, so they are told to carry an emergency dose of epinephrine at all times. Epinephrine works by reducing swelling in the airway and increasing blood flow in the veins. Out of concern many public and private places have also begun to carry injectable epinephrine but with no generic form of the easiest kind of device there have been complaints of price gouging.

No more. 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.

The EpiPen is intended to automatically inject a dose of epinephrine into the 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. Epinephrine auto-injector products are “combination products” because they consist of a drug (epinephrine) and a device (the auto-injector). Though the mechanisms for both are well known for a century the FDA still considers each product new. That has hindered competition, especially in the generic market where profits will be lower, so FDA has been helping companies navigate their complex process.

In this case, the FDA has published three draft or final guidances since 2009 related to the development of generic epinephrine auto-injectors. In addition, as with brand-name drugs, the FDA inspects manufacturing and packaging facilities for generic drugs to ensure that they are

capable of consistently producing quality products.

This epinephrine injection (auto-injector) is intended for immediate administration.

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