

controls before marketing. In my opinion, someone needs to build on this history and detail the fine work of the FDA from 1981 through the passing of the Drug Quality and Safety Act of 2013. The following are a couple of key acts that have been signed into law since 1981.

The 1988 Food and Drug Administration Act

The 1988 Food and Drug Administration Act officially established the FDA as an agency of the Department of Health and Human Services with a commissioner of food and drugs appointed by the president with the advice and consent of the Senate. This act identified the responsibilities of the HHS secretary and the commissioner for research, enforcement, education, and information.¹²

The Prescription Drug Marketing Act of 1988

The Prescription Drug Marketing Act of 1988 bans the diversion of prescription drugs from legitimate commercial channels. The new law requires drug wholesalers and distributors to be licensed by the states, restricts reimportation from other countries, and bans sale, trade, or purchase of drug samples, and traffic or counterfeiting of redeemable drug coupons.¹³

Food and Drug Administration Modernization Act of 1997

This act reauthorizes the Prescription Drug User Fee Act of 1992 and mandates the most wide-ranging reforms in agency practices since 1938. Provisions include measures to accelerate review of devices, regulate advertising of unapproved uses of approved drugs and devices, and regulate health claims for foods.¹⁴

FDA Summary

Regarding pharmaceutical drugs, the men and women of the FDA have a very difficult task. They are responsible for protecting the public health by ensuring the safety, security, and efficacy of these drugs. They have also been relied upon for the past 150+ years to use science-based information to promote innovation to help make our pharmaceutical drugs safer, more effective, and more affordable. It is not easy to take a law and flesh out the regulations and details supporting the law, protecting the public health