

Volume 1, Issue 2

FDA will begin routine inspections of large farms in spring 2019.

Routine inspections to verify compliance with the requirements of the Produce Safety Rule established by the FDA Food Safety Modernization Act will begin in spring 2019 for large farms other than sprouts operations. FDA has published various resources in its website to aid industry in complying with the rule.

Food

FDA has cancelled and removed all food registrations for which biennial renewal was not completed by Dec 31, 2018. There are lots of detentions at the ports countrywide for lack of a valid registration number. Also, due to work backlog caused by the recent US government shutdown, FDA is taking longer time than usual to process food registrations submitted.

Drug

The Division of Medication Error Prevention and Analysis, a part of CDER, monitors and analyzes medication error reports associated with marketed drug products which includes OTC drugs and Prescription, generics and other therapeutic biologicals. So all drug manufacturing companies are encouraged to have proper naming labeling, packaging and design for CDER regulated drug products.

Medical Devices

FDA has deactivated and removed all medical device establishment registration for the companies who did not renew their registration before Dec 31, 2018. All Medical device establishments who manufacture/ contract manufacture/ specification developers/ labelers/ packers/ importers are responsible to complete the registration and pay FDA fees of \$4884 before exporting or importing their products.

Cosmetics

It's against the law for a cosmetic to contain any ingredient that makes the product harmful when consumers use it according to directions on the label, or in the customary way. FDA has issued specific regulations prohibiting or restricting the use of certain ingredients in cosmetics.

Liberty Management Group Ltd is a leading FDA consulting firm providing assistance with various FDA regulations.



Liberty Management Group Ltd.
75 Executive Dr, Ste 114
Aurora, Illinois - 60504, USA
www.fdahelp.us
630-270-2921