FDA NEWS

MARCH 2019

A MONHTLY NEWSLETTER BROUGHT TO YOU BY LIBERTY MANAGEMENT GROUP LTD.

Volume 1, Issue 3

FDA warns against illegally marketed unapproved drugs

FDA is taking action against the companies which market unapproved drugs claiming to treat addiction, chronic pain, cancer and other serious conditions. As per FD&C act, selling these unapproved drug products is a violation of law.

Food

- FDA has issued 17 warnings letters against various domestic and foreign companies selling products that are sold as dietary supplements, which are unapproved new drugs or misbranded drugs that claim to prevent, treat or cure Alzheimer's disease and several other serious diseases and health conditions.
- 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.

Drug

FDA has issued warning letters to the companies that markets unapproved new drugs that contains cannabidiol (CBD). FDA is taking action against the firms on a case to case basis according to the label claims. It is important to note these products are not approved by FDA and manufacturers' needs to make sure that their labelling are in compliance with FDA regulations before marketing these products.

Medical Devices

FDA has changed the UDI compliance dates for Class I reusable devices that are required to have UDI on the device itself to September 24, 2020. For Class I and unclassified devices manufactured and labeled on or after September 24, 2018 - September 24, 2022. For Finished Class I and unclassified devices manufactured and labeled before September 24, 2018 - September 24, 2022.

Cosmetics

FDA has found asbestos in cosmetic products sold by few American retailers. 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