FDA NEWS

AUGUST 2019

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

Volume 1, Issue 8

FDA has announced Medical Device User Fees for Fiscal Year 2020 starting from October 1, 2019 through September 30, 2020.

Food

- FDA announces FY 2020 Fee Rates for Voluntary Qualified Importer Program and Third-Party Certification Program.
- FDA amends the color additive regulations to provide for the safe use of soy leghemoglobin as a color additive in ground beef analogue products.
- FDA announces FY 2020 fee rates for certain domestic and foreign facility re-inspections, failures to comply with a recall order and importer re-inspections, as authorized under FSMA.

Drug

FDA has informed that it will begin deactivating drug listing records in its database that are not properly listed in accordance with FDA requirements as these drug listings are not certified as being active and up to date or the manufacturing establishment is not registered with FDA. FDA wants the registrants to notify if the drugs are not in commercial distribution and ask them to put an end marketing date in the listings. Also, FDA requires firms to submit drug listings updates if there are any material changes to information previously submitted which includes change in manufacturing establishment(s). Drugs with inactivated listing records cannot be legally marketed or imported in the US.

Medical Devices

FDA has announced user fees for FY 2020. The annual establishment registration fee must be paid between October 1, 2019, and December 31, 2019. For FY 2020, the registration fee for each establishment is $5,236. All establishments are required to pay the establishment registration fee. There are no waivers or reductions for small establishments, businesses, or groups.

Cosmetics

Manufacturers of several cosmetic products have recalled their products because of incorrect ingredient listing on the label. FDA considers such products misleading.

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