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FDA Activities are limited due to Government shutdown

Beginning from December 22nd FDA activities are limited due to employee shortage and limited funding. Around 41 percentage of employees are furloughed as per present FDA update, which means all FDA processing will be delayed. During the lapse period, FDA will continue vital activities, to the extent permitted by the law, that are critical to ensuring public health and safety in the United States.

Food

The biennial registration renewal period for food is over. If you did not renew your food facility registration by December 31, 2018, your registration is no longer valid. You will need to re-register your facility in order to be able to market your products in USA.

Drug

All drug establishments who did not renew their establishment registration for FY 2019 can still renew their registration and list their drugs with FDA. However, the companies who request for new labeler code, FDA is not processing the request during the "Lapse period". But the companies with labeler code can still proceed with drug listing.

Medical Devices

Since FDA does not have legal authority to accept any fee payments during lapse period, FDA system is not generating PCN (payment confirmation number) which is mandatory to proceed with renewal of medical device establishments. However, the establishments who had already completed the renewal for FY 2019 will be able to proceed with device listings. So, everyone must wait to proceed with their medical device establishment registration renewal until the government shutdown is resolved.

Cosmetics

The processing times for cosmetic registrations, inspections, ingredient filings have increased due to US government shutdown.

Liberty Management Group Ltd. will continue to support our clients during the Govt shutdown, you can reach LMG at 630-270-2921 or e-mail: info@fdahelp.us



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