FDA NEWS

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FDA warns manufacturers of Homeopathic Products

FDA has issued warning letters to the manufacturers of homeopathic products for cGMP violations. FDA encourages health care professionals and consumers to report adverse events to FDA's MedWatch program.

Food

- FDA's VQIP application period is extended until July 31, 2019. This voluntary fee-based program provides expedited review & import entry of human & animal foods into USA for participating importers.

- FDA has issued warning letters to several companies whose products are marketed as dietary supplements and labeled to contain DMHA. FDA has determined that DMHA is either a "new dietary ingredient" for which FDA has not received the required New Dietary Ingredient Notification or that it is an unsafe food additive. FDA considers dietary supplements containing DMHA to be adulterated.

- ANSI-ASQ has accredited LSQA S.A. of Montevideo, Uruguay as a certification body authorizing them to conduct food safety audits and issue food and facility certifications within the scopes of their programs. Certifications issued by a certification body can be used by importers to establish eligibility for participation in Voluntary Qualified Importer Program (VQIP) or to certify imported products when requested by FDA.

Drug

FDA is now requesting the manufacturers of OTC sunscreen products to include MUsT (maximal usage trial) study data to assess the absorption of drugs into the body. A maximal usage trial (MUsT) is a standardized approach to assess the absorption of all drugs, including topical drugs, into the body.

Medical Devices

FDA has issued guidance to put UDI on the label of convenience kit. As per the guidance, the label of each individual device within the container is not required to bear a UDI, provided that a UDI is available on the label affixed to the immediate container of the kit. Ref: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-convenience-kits

Cosmetics

FDA has issued warning letters to several cosmetic companies marketing products in US with unapproved drug claims such as help reduce headaches, fever reducer, relieving migraines, reduce inflammation etc.

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