

COMPLIANCE ANNOUNCEMENT



Update on Light-emitting Diode (LED) Reporting to FDA

The US Food & Drug Administration (FDA) is providing this update to clarify expectations regarding Light-emitting diodes (LED) reporting.

The FDA has regulatory authority over radiation-emitting electronic products, which are defined in 21 CFR 1000.3 as any electrically-powered product that can emit any form of radiation on the electromagnetic spectrum. As such, reporting to FDA upon importation of radiation-emitting electronic products is required. LED products emit visible optical radiation, which qualifies them to be radiation-emitting electronic products and gives FDA regulatory authority. The level of information to be provided varies based on whether there is a performance standard, but the general regulatory authority remains with the FDA.

Recently, the FDA became aware that information was not being transmitted to their administration for review of imported LED products. To rectify this, the FDA updated the FD Flag for LEDs under HTS code 8541.40.2000, which is now set at FD2. The FDA expects the transmission of entry data for products falling under this HTS code. LED products used for general or local area illumination, such as lamps and lightbulbs, are of special interest to the FDA and must be submitted to the FDA for review.

However, the FDA does not expect the transmission of entry data for finished products which incorporate LEDs as indicator lights, such as in toys, tablets, cellular devices, tablet devices, shoes, household appliance and entertainment systems, remote controls, or other products not otherwise regulated by the FDA in another capacity. These types of products do not fall under HTS code 8541.40.2000 and are not indicated for entry submission to the FDA.

If your product may be subject to this additional agency release/reporting and you have questions regarding this matter, please contact your local KWE Brokerage Servicing branch.

Disclaimer: The subject matter of this newsletter is provided for informational purposes only. All data is obtained from public sources and is believed to be true and accurate. KWE is not responsible or liable for any inaccurate information contained herein.