Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 300.100 Inspection of Manufacturers of Device Components (CPG 7124.15)

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BACKGROUND:

Section 510(h) of the Federal Food, Drug, and Cosmetic Act declares that all registered firms are subject to inspection pursuant to Section 704. Some manufacturers have been confused by 21 CFR 807.65, believing that exemption from registration also exempts them from inspection. This is not true. As defined under Section 201(h) of the Act, devices include components of devices, making manufacturers of device components subject to the provisions of section 704. Title 21 CFR 807.65(a) exempts manufacturers of medical device components from the registration and listing provisions of section 510 of the Act, if those components are the only items the manufacturer produces which have health care applications and they are sold only to other manufacturers. The exemption does not apply to manufacturers of components described in 21 CFR 807.20(a)(5) unless they are marketed only to registered device establishments for further processing. The exemption applies only to registration and listing.

POLICY:

*Exemption from registration under 21 CFR 807 does not exempt the manufacturer of device components from inspection under section 704 of the

act.*

All manufacturers of device components are subject to inspection under section 704 of the Act.

Material between asterisks is new or revised

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