CPG Sec. 110.200 Export of FDA Regulated Products from U.S. Foreign Trade Zones

BACKGROUND:

From time to time industry inquires whether regulated products can be manufactured in a Foreign Trade Zone (Free Trade Zone) and exported without meeting the requirements of the laws and regulations administered by the Food and Drug Administration.

Foreign Trade Zones are provided in the United States by the U. S. Customs Service for the trade to hold or otherwise manipulate goods for an unlimited period of time awaiting a favorable market in the U. S. or nearby countries without being subject to customs entry, payment of duty, tax, or bond. The location of an establishment in a Foreign Trade Zone has absolutely no bearing on the jurisdiction of the Food and Drug Administration or the applicability of the laws it administers.

POLICY:

For the purposes of the laws enforced by the FDA, Foreign Trade Zones are part of the United States and the movement of regulated products into or out of such zones, including export, constitutes interstate commerce. Therefore, regulated products in Foreign Trade Zones must comply with those laws that come within the purview of FDA.

Reference: See United States v. Yaron Laboratories, Inc., 365 F. Supp. 917 (N.D Calif., 1972.)

Material between asterisks is new or revised

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Chapter 1 - General