

CPG Sec. 110.600 FDA Authority Over Products of Foreign Origin Located in Foreign Trade Zones, Bonded Warehouses or on Bonded Carriers

BACKGROUND:

On occasion, questions have been raised concerning FDA's authority over foreign origin products brought into the U.S. for which no entry has been filed or importation has not been made. These products are usually located in U.S. Foreign (Free) Trade Zones. However, they may also be found in bonded warehouses or in bonded vehicles.

As stated in CPG 7150.11 (See Sec. 110.200) "Export of FDA Regulated Products from U.S. Foreign Trade Zones", such zones are provided by the U.S. Customs Service as a means of avoiding payment of duty, tax, and bond if the goods are not intended for entry for consumption, to delay such payment until actual entry for consumption is made.

Products of foreign origin located in Foreign Trade Zones or in bonded warehouses are in the United States, are in interstate commerce and are therefore subject to the laws administered by FDA.

Products entered for transportation and exportation (in bond for transportation through the United States by a bonded carrier without appraisement or the payment of duties) are also subject to the laws administered by FDA.

POLICY:

FDA has the authority to regulate products of foreign origin brought into the U.S. whether or not entry has been filed. The location of goods (truck, bonded warehouse, Foreign Trade Zones, etc.) does not affect FDA's authority over the goods.

Products not imported or offered for import:

Those products of foreign origin not offered for import but located within the legal boundaries of the U.S. are to be regulated under the domestic provisions of statutes.

Products imported or offered for import:

Those products (whether in Foreign Trade Zones, bonded warehouses, etc.) which have been offered for entry and those already imported but still in import status are regulated under the provisions of section 801 of the FD&C Act or 360(a) of the RCHS Act.

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