Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 442.100 New Drugs - Export (CPG 7132c.01)

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BACKGROUND:

The question has been raised as to whether or not a drug for which an NDA has been submitted, could legally be exported for commercial distribution before the NDA was approved.

POLICY:

Section 801(d) of the Act provides an exemption from the adulteration and misbranding provisions only and does not authorize exportation of a new drug that is not covered by an approved NDA.

However, under the provisions of 21 CFR 312.1, a new drug, limited to investigational use may be exported only for purposes of clinical investigation and not where the drug is intended for commercial marketing, or use in routine medical practice.

NOTE: See CPG 7150.11 (See Sec. 110.200 for this CPG.) covering export of FDA controlled products (including NDA/IND drugs) from Foreign Trade Zones.

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