

CPG Sec. 110.900 Imported Products - Lack of English Labeling

BACKGROUND:

Violative imported products should preferably be handled at the port of entry. However, all imported products entered into the United States are not sampled or examined. In fact, most imported articles subject to the agency's jurisdiction are given a "May Proceed Notice" upon entry and are not examined prior to entering domestic commerce. Although the agency attempts to sample or examine as many potentially violative products as possible, it is inevitable that some violative foreign products enter into United States commerce.

On occasion, violative imported products that are labeled solely in a foreign language [violation of 21 CFR 101.15(c)(1) for foods, 21 CFR 201.15(c)(1) for drugs, 21 CFR 501.15(c)(1) for animal drugs, 21 CFR 701.2(b)(1) for cosmetics, and 21 CFR 801.15(c)(1) for medical devices] are able to enter into United States commerce without being detained when they are in import status. At some point later, these foreign labeled products may be brought to the agency's attention by a complaint. When this occurs, the most desirable solution is voluntary correction (e.g., relabeling or destruction). Failing voluntary correction, the action of choice is seizure of the misbranded lot.

NOTE: These sections contain an exemption which allows for labeling in the predominant language other than English, in the Commonwealth of Puerto Rico or in a U.S. territory.

REGULATORY ACTION GUIDANCE:

Violative imported products should be dealt with at the port of entry whenever possible. In the few instances where products labeled solely in a foreign language gain entry without examination, district offices are authorized to refer for direct reference seizure to the *Office of Chief Counsel (GCF-1)* through the Division of Compliance Management and Operations (HFC-210), seizable size lots (\$1,000 or more) of foods, drugs, animal feeds or drugs, cosmetics and medical devices, which are labeled solely in a foreign language when the owner or other party controlling the lot refuses to voluntarily correct the violation. In instances where this occurs, the district should take appropriate steps to assure that future import shipments either comply with our laws or are detained at the port of entry. This may entail intensive coverage of FDA regulated commodities imported by that firm.

For lots valued under \$1,000 attempt to obtain state or local condemnation.

Material between asterisks is new or revised

Issued: 3/1/84

Revised: 8/31/89, 3/95, 8/96

More in Compliance Policy Guides

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

Foreword: Compliance Policy Guides (CPGs)

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)

Chapter 1 - General

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116280.htm)

Chapter 2 - Biologics

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116336.htm)

Chapter 3 - Devices

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116801.htm)

Chapter 4 - Human Drugs

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119572.htm)

Chapter 5 - Food, Colors, and Cosmetics

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)

Chapter 6 - Veterinary Medicine

(/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm)