CPG Sec. 300.400 Contamination of Devices Labeled as Sterile

BACKGROUND:

Certain devices labeled as sterile are frequently used on debilitated patients whose resistance to microorganisms is lower than that of a normal healthy person.

Recent experience has demonstrated that devices labeled as sterile and intended for use under sterile conditions may be nonsterile.

POLICY:

A device labeled as sterile which fails to pass USP tests for sterility is adulterated under Section 50l(c) in that its purity and quality falls below that which it is represented to possess and is misbranded under 502(a) in that the label statement "sterile" is false or misleading as applied to a product which is not sterile, but is contaminated with viable organisms.

Device nonsterility should be treated as top priority, because of the seriousness of the health hazard posed by the microbial contamination of sterile products. The responsible firm should be notified of our finding to afford it the opportunity to voluntarily recall its device.

Appropriate legal action and/or recall should be recommended when the examination of a sterile device reveals defective packaging (separated seams, torn or punctured outer wrap) and there is no other protection of package contents. Confirmation of nonsterility by sterility testing is unnecessary in these cases. Inspection reports, exhibits and the results of analysis for defective packaging should be included in the district recommendation to *HFZ-300*. The results of analysis should include the number of units examined, the number of units found defective, the types of defects identified and the range in size and numbers of holes or broken seams found per unit.

In situations where there is more than one wrap or there are questions regarding whether the nature of the packaging defect meets the conditions outlined in this guideline, the district should consult with *HFZ-300*.

Material between asterisks is new or revised

Issued: 8/23/74

Reissued: 6/11/76

Revised: 10/1/80, 9/24/87, 3/95

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)