

CPG Sec. 335.800 Clinical Thermometer - Adulteration; Misbranding Defects

BACKGROUND:

The FDA has stated that NBS Commercial Standard CS 1-52, which became a Voluntary Product Standard PS 39-70, would be used as the basis for regulatory action against clinical thermometers (mercury-in-glass, reusable). The voluntary standard has now developed into an ASTM Standard E 667-81. The following criteria reflect this updated material.

POLICY:

If clinical thermometers are found to be outside the specifications for accuracy as found in the ASTM E 667-81 Standard they will be considered to be violative.

REGULATORY ACTION GUIDANCE:

The following represents criteria for direct reference seizure to *the Office of Medical Device and Radiological Health Operations (OMDRHO) with consult to* the Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration.

Sample Size Defects

15 2 or more

24 3 or more

A clinical thermometer is considered defective for accuracy if the following accuracy cannot be met. (Round to one decimal place)

Celsius Scale Fahrenheit Scale

Less than 35.80C 0.30C Less than 96.40F 0.40F

35.80C to 37.00C 0.20C 96.40F to 98.00F 0.30F

37.00C to 39.00C 0.10C 98.00F to 102.00F 0.20F

39.00C to 41.00C 0.20C 102.00F to 106.00F 0.30F

Greater than 41.00C 0.30C Greater than 106.00F 0.40F

SPECIMEN CHARGES:

That the article of device is adulterated when introduced into and while in interstate commerce within the meaning of 21 U.S.C. 351(c) in that its quality falls below that which it purports or is represented to possess.

That the article of device is misbranded when introduced into and while in interstate commerce (or after receipt in interstate commerce if applicable) within the meaning of 21 U.S.C. 352(a) in that the label statements "Accurate", "Dependable", "Easy Reading", and "*** this thermometer conforms to all of the requirements established in ASTM Standard E 667-81" are false *or* misleading or are otherwise contrary to fact.

Material between asterisks is new or revised

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