

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D–0043]

### **Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy; Draft Revised Compliance Policy Guide; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for FDA staff and industry entitled “Compliance Policy Guide (CPG) Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23).” This draft CPG provides guidance concerning accuracy and exhaust rate criteria for sphygmomanometers. This draft guidance is being issued for public comment only and will not be implemented until a final CPG is announced in the **Federal Register**.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication in the **Federal Register***].

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FAX your request to 240–632–6861. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit

electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240-632-6851.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In 1992 and 1994, the Association for the Advancement of Medical Instrumentation (AAMI) issued two revised standards that were approved by the American National Standards Institute (ANSI) namely, “ANSI/AAMI SP9-1994 American National Standard Non-Automated Sphygmomanometers” and “ANSI/AAMI SP10-1992 American National Standard for Electronic or Automated Sphygmomanometers.”

As amended by the FDA Modernization Act of 1997 (FDAMA), section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) allows FDA to recognize consensus standards, established by international and national standard development organizations, for use in satisfying portions of device premarket review submissions or other requirements. FDA now recognizes the complete standards ANSI/AAMI SP9-1994 and ANSI/AAMI SP10-1992 for the purpose of premarket clearance (63 FR 55617, October 16, 1998; 67 FR 1774, January 14, 2002). To be consistent with current industry practice, FDA intends to use the accuracy and exhaust rate criteria identified in these recognized consensus standards as guidance for testing, surveillance, and compliance purposes, as well as for premarket clearance. Therefore, this

draft revised guidance reflects the accuracy and exhaust rate criteria in the currently recognized revisions of these two voluntary standards.

## **II. Significance of Guidance**

This draft guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In accordance with FDA's good guidance practices regulation (21 CFR 10.115), this draft document is considered a level 1 guidance. This draft guidance is being issued for public comment only and is not in effect at this time. Only after a notice of availability is published in the **Federal Register** for the final document will the agency implement the guidance.

## **III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The agency will review all comments, but in issuing final guidance, need not specifically address each comment. If appropriate, the agency will make changes to the guidance in response to comments. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## **IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/ora/compliance1ref/revisions.htm*.

Dated: February 10, 2005.

**John Marzilli,**

*Acting Associate Commissioner for Regulatory Affairs.*

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