

CPG Sec. 310.200

Sphygmomanometers - Rx Legend

BACKGROUND:

The Food and Drug Administration has in the past advised distributors of blood pressure measuring devices (sphygmomanometers) that such devices should be distributed only under the prescription legend. Some imported devices have been detained for failure to bear the legend. This was based on the opinion of our medical advisers that a blood pressure reading requires interpretation and evaluation by a physician in order to have any real significance.

The status of such devices has been reviewed and it is now apparent that, although medical opinion could be obtained regarding the advisability of a prescription legend on sphygmomanometers, we do not now have evidence of injury or hazard to health resulting from lay use of these devices.

POLICY:

We are not prepared to initiate regulatory action based solely on the lack of the prescription legend on sphygmomanometers.

Material between asterisks is new or revised

Issued: 1/1/73

Revised: 10/1/86, 9/24/87

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