CPG Sec. 345.200 Diaphragms - Rx Devices

BACKGROUND:

The Federal Food, Drug, and Cosmetic Act (the Act), section 502(f)(1), provides that the labeling of a device shall bear adequate directions for use unless exempted from this requirement by regulation. 21 CFR 801.109 provides an exemption in the case of those devices which cannot be safely and efficaciously used except under medical supervision.

A physician must determine the size and type of diaphragm for the patient. For proper results the device must be placed by the physician and inspected at intervals to avoid injury to the patient.

POLICY:

Diaphragms are devices which shall be distributed by prescription only. Any diaphragm that fails to bear the prescription legend is misbranded under *section 502(f)(1) of the Act.*

Material between asterisks is new or revised

Issued: 4/29/76
Revised: 9/24/87

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