CPG Sec. 300.300 Ineffective Devices - 502(f)(l) Labeling Requirements

BACKGROUND:

It is our concept of section 502(f)(l) *of the Federal Food, Drug, and Cosmetic Act (the Act)* and the pertinent regulations that an ineffective device cannot be brought into compliance with that section. *21 CFR* 80l.5 defines "adequate directions for use" as meaning directions under which the layman could use a device for the purposes for which it is intended. This wording implies that the directions for use must be such as to enable the user to employ the article successfully for the intended purpose. Obviously, it is not possible to prepare directions that would enable the layman to use a device which is not effective for any medical purpose.

POLICY:

Ineffective devices are misbranded within the meaning of Section 502(f)(l) of the act. Such devices cannot meet the criteria for "adequate directions for use" for layman use (21 CFR 80l.5) or the exemption for use by licensed practitioners under 21 CFR 80l.l09. Prior to preparing a recommendation for legal action, the district should assure that the situation meets the conditions for considering regulatory action stated in Compliance Policy Guide 7150.10, Health Fraud - Factors in Considering Regulatory Action.

(Please Note - The Health Fraud definition includes the "... promotion, advertisement, distribution or sale of articles, intended for human or animal use ...").

Material between asterisks is new or revised

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Foreword: Compliance Policy Guides (CPGs)