CPG Sec. 355.200 Electrical Muscle Stimulators

BACKGROUND

Certain importers, manufacturers, and individuals are promoting and selling Electrical Muscle Stimulators (EMS) directly to salons and the general public for a variety of uses including body slimming and trimming, body shaping and contouring, weight loss, bust development, and wrinkle and cellulite removal. FDA has seen no valid scientific data to support the use of EMS devices for these conditions and purposes.

The health care community recognizes EMS devices as effective for muscle reeducation, relief of muscle spasm, increasing range of motion, disuse atrophy therapy, increased local blood circulation, and immediate postsurgical stimulation of calf muscles to prevent venous thrombosis. Adequate directions for safe and effective use by the laity for these devices cannot be written. FDA, therefore, regards EMS devices to be subject to 21 CFR 801.109 as prescription devices.

POLICY:

EMS devices may only be lawfully sold by or on the order of practitioners licensed by state law to use or order the use of such devices. Such devices may only be sold to, or used by, laymen on the prescription or other order of a licensed practitioner in the course of his or her professional practice.

An EMS device labeled for conditions or purposes other than those recognized by the consensus of medical opinion as referenced above, are considered misbranded under Section 502(a) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the labeling is false *or* misleading. In addition, an EMS device which does not comply with 21 CFR 801.109 is misbranded pursuant to subsection 502(f)(1) of the Act in that the labeling fails to bear adequate directions for use. Prior to submitting a recommendation for legal action, the appropriate division within the Office of Medical Device and Radiological Health Operations program should assure that the situation meets the conditions for considering regulatory action in CPG 7150.10 (See Sec. 120.500), 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 ...")*. Where possible, action should be taken against the devices in the possession of the manufacturer or primary distributor, rather than at a salon. Salon activities generally should be turned over to local and state licensing agencies since salon activities fall within their jurisdiction.

Material between asterisks is new or revised

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