

CPG Sec. 355.300 Ion Generating Devices

BACKGROUND:

There are a number of ion generating devices, both negative and positive, which are being promoted for the treatment of various diseases. When medical claims are made for these ion generating devices, they are subject to the *Federal* Food, Drug, and Cosmetic Act. Until the medical claims can be supported with well controlled and valid scientific studies, these devices are considered misbranded. Should the ion generator produce ozone, it would be subject to 21 CFR 801.415, provided the intended use brings it within the definition of a device. For the most part labeling for ion generators currently being marketed claim the absence of, or very low levels, of ozone production. Truthfulness of such claims require verification.

POLICY:

Ion generating devices promoted for medical use are subject to the requirements of the Federal Food, Drug, and Cosmetic Act. Such devices labeled with unsupported medical claims are in violation of 502(a) and 502(f)(1). If encountered, follow 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 animals use ...")*.

Material between asterisks is new or revised

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