CPG Sec. 396.400 Policy on Warned on Sunlamp Products

BACKGROUND:

The Center for Devices and Radiological Health has found numerous imported and domestic sunlamp products labeled in such a way as to render the label illegible and/or inaccessible to view by the consumer under normal conditions of purchase and use.

Sunlamp products are electronic products as defined by Section *531(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA)* and medical devices as defined by Section 201(h)(3) [21 U.S.C. 321(h)(3)]. The performance standard for sunlamp products (21 CFR 1040.20) promulgated under authority of Section *534(a)(1)* of the *FFDCA,* requires that labels containing specific information be permanently affixed or inscribed on an exterior surface of the product so as to be legible and readily accessible to view when the product is fully assembled for use. The general labeling provisions for medical devices under 21 CFR 801.5 require adequate directions for use be provided to the user and 21 CFR 801.15 defines the prominence of the required label statements for devices.

POLICY:

The intended purpose of the warning label required on sunlamp products is to provide that information necessary for the consumer to make an informed decision regarding the risks of using sunlamp products and to provide adequate directions for skin tanning. Therefore, the label must be legible and conspicuously placed on the product so as to render it likely to be read by the user under normal conditions of purchase and use. The Agency will consider sunlamp products to be noncompliant with the performance standard under Section *534(a)(1)* of the *FFDCA* and misbranded under Section 502(c) of the *FFDCA* if the required information lacks prominence and conspicuousness for the following reasons:

1. The failure of the label required under 21 CFR 1040.20(d)(1) to appear on a prominent part or panel which is presented or displayed under normal conditions of purchase and/or use.
2. The failure to provide adequate space for the label required under 21 CFR 1040.20(d)(1).
3. The inability of an individual with 20/20 corrected vision to read the label from a distance of approximately one meter because of inadequate lettering size and background contrast. Note: Lettering of ten (10) millimeters (height) for the word "DANGER" and five (5) millimeters for the

rest of the label information is normally adequate to meet the visibility requirements.

Material between asterisks is new or revised.

Issued: 5/1/86
Revised: 3/95

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