DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 25 1985

TO: ALL MANUFACTURERS, IMPORTERS AND POTENTIAL MANUFACTURERS OF SUNLAMP PRODUCTS.

SUBJECT: POLICY ON WARNING LABEL REQUIRED 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 355(2) [42 U.S.C 263c(2)] of the Radiation Control for Health and Safety Act of 1968 (RCHSA) and medical devices as defined by Section 201(h)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C) [21 U.S.C.321(h)(3)]. The performance standard for sunlamp products (21 CFR 1040.20) promulgated under authority of Section 358 of the RCHSA, 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 358(a)(1) of the RCHSA and misbranded under Section 502(c) of the FD&C Act if the required product label is not legible and accessible to view for the following reasons:

1. The label required under 21 CFR 1040.20(d)(1) does not appear on a prominent part or panel which is presented or displayed under normal conditions of purchase and/or use.

2. Adequate space is not provided for the required label or the label is not prominently displayed on the device.

3. The normal individual can not read the label from a distance of one meter because of inadequate lettering size and background contrast. Lettering of ten (10) millimeters (height) for the word "DANGER" and five (5) millimeters for the rest of the label information is recommended to meet the visibility requirements.

Walter E. Gundaker, Director
Office of Compliance
Center for Devices
and Radiological Health