DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

SEP 2 1986

TO: ALL MANUFACTURERS, IMPORTERS AND POTENTIAL MANUFACTURERS OF SUNLAMPS

SUBJECT: POLICY ON LAMP COMPATIBILITY

BACKGROUND:

The amended performance standard for sunlamp products (21 CFR 1040.20) was published in the September 6, 1985, issue of the Federal Register and will become effective September 8, 1986. Any ultraviolet lamp (intended to be used in sunlamp products) and sunlamp products manufactured on or after that date must comply with the amended standard.

The amended standard requires the user instructions of an ultraviolet lamp not accompanying a sunlamp product to contain a clear identification by brand name and model designation of all lamp models for which replacement lamps are promoted, if applicable [21 CFR 1040.20(f)(2)(iii)]. As stated in the preamble of the amendments to the standard (Federal Register issue of September 6, 1985) the promotion of incompatible lamps will be considered as marketing a falsely certified product.

The Center for Devices and Radiological Health (CDRH) has been asked what criteria will be used to evaluate lamp compatibility.

POLICY:

A replacement lamp will be considered compatible with (or equivalent to) another (original) lamp if:

1) The replacement lamp will not cause any sunlamp product intended to use the original lamp to fail to comply with the standard or to become defective as defined by 21 CFR 1003.2, and;

2) the lamp is as effective, within plus or minus ten percent, as the original lamp, in causing erythema and melanogenesis.

It should be noted that the above criteria apply to the sunlamp product exposure schedule and maximum timer interval which must appear on the product's labeling. The manufacturer should use the following procedure to establish conformance with criterion number 2 above:

1) Calculate the recommended maximum exposure time for a single original lamp (Y) using the CDRH August 21, 1986, guidance (POLICY ON MAXIMUM TIMER INTERVAL AND EXPOSURE SCHEDULE FOR SUNLAMP PRODUCTS).

2) Calculate the recommended maximum exposure time for a single replacement lamp (X) using the same method.

3) Compare the values, if the value for the replacement lamp (X) is within plus or minus 10% of the value of the original lamp (Y), the lamp would be considered compatible [Y= X +/- 10%].

The distance(s) used for this comparison should represent the typical use distance range in products using the original (Y) lamp.

The CDRH welcomes comments on this policy.

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