CPG Sec. 396.200 Exemption for Certain Sunlamp Product Purchaser Records

BACKGROUND:

The regulations in 21 CFR 1002 under the **Federal Food, Drug, and Cosmetic Act, Chapter V, Subchapter C - Electronic Product Radiation Control* require, among other things, that a manufacturer of an electronic product subject to a performance standard maintain purchaser records received from dealers or distributors (21 CFR 1002.30(b)(2)). Furthermore, 21 CFR 1002.40(a) requires that dealers and distributors of products for which the retail price is not less than $50 obtain such information as is necessary to permit tracing of specific products to specific purchasers. The information required to be obtained by dealers and distributors is specified in 21 CFR 1002.40(b) and must be forwarded immediately to the appropriate manufacturer of the electronic product unless the dealer or distributor elects to hold and preserve such information (21 CFR 1002.40(c)).

Sunlamp product manufacturers have presented their contention to the *Center for Devices and Radiological Health (CDRH)* that the number of relatively inexpensive portable home sunlamp products sold cannot justify the additional burdens and costs involved in setting up a complete system which would enable the tracing of these products to specific use locations. The *CDRH* has seriously considered this request and agrees that an exemption from certain recordkeeping requirements is warranted.

The intent of the cited regulations is to provide the necessary information needed for a manufacturer to identify and locate the first purchasers of the products in the event of recall. It should also be noted that in 21 CFR 1002.50(b) the Director of the *CDRH* may exempt a manufacturer from all or parts of the recordkeeping requirements.

POLICY:

Portable home sunlamp products and ultraviolet lamps intended for use in such products which would be subject to the dealer and distributor recordkeeping requirements by virtue of their retail price are hereby exempted under the authority of 21 CFR 1002.50 from the requirements of 21 CFR 1002.40 and 1002.41, subject to the following conditions:

1. The manufacturer must place a postage prepaid and preaddressed post card in the package for each exempted sunlamp product or exempted ultraviolet lamp.
2. The post card must provide spaces for the purchaser to record his or her name and mailing address, model and serial number of the product, and the date of the sale.
3. The following statement must appear on the post card: "This product is required to meet the Safety Performance Standard for Sunlamp Products issued by the Federal Food and Drug Administration. Please complete and return the self-addressed postage prepaid post card to ... (insert manufacturer's name) so that we may contact you in the event it becomes necessary to correct, free of charge, any safety related defect."
4. The manufacturer must maintain and preserve completed post card records obtained from purchasers in the manner prescribed by 21 CFR 1002.31 for maintenance and preservation of records received pursuant to 21 CFR 1002.41.

The *CDRH* believes these conditions will significantly reduce the burden upon dealers, distributors, and manufacturers of these products, while at the same time providing some means of locating purchasers in the event of a recall.

This exemption and the conditions noted do not apply to suntanning booths or sun beds and couches.

Material between asterisks is new or revised

Issued: 4/1/81
Revised: 3/95

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