DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 16 1981

TO: Manufacturers and Potential Manufacturers of Sunlamp Products (Including Tanning Booths)

SUBJECT: Exemption from Reporting and Recordkeeping Requirements for Certain Sunlamp Product Manufacturers

BACKGROUND: The regulations in 21 CFR 1002 promulgated under the Radiation Control for Health and Safety Act of 1968 require, among other things, that a manufacturer of an electronic product subject to a performance standard submit an initial report, annual reports, and model change reports, as applicable, to the Director, Bureau of Radiological Health (21 CFR 1002.10, 1002.11 and 1002.12). Furthermore, a manufacturer of an electronic product subject to a performance standard is required to maintain certain records including a description of the quality control procedures with respect to the product's radiation safety, results of life testing and copies of written communications between the manufacturer, dealers, distributors and purchasers regarding radiation safety (21 CFR 1002.30(a)) and preserve such records for a period of 5 years from the date of the record (21 CFR 1002.31(a)).

The Bureau's experience in the enforcement of the performance standard for sunlamp products (21 CFR 1040.20) indicates that the above referenced reporting and recordkeeping requirements seem to be an overburden for an individual or firm who manufactures on a one time or infrequent basis a small number of sunlamp products (usually less than 10) for his own use. Exempting this type of manufacturer from the referenced reporting and recordkeeping requirements under certain conditions would not compromise the spirit or purpose of the Act since FDA can determine compliance through product inspections.

EXEMPTION: Any person who manufactures less than 10 sunlamp products for use in their own commercial suntanning facilities is hereby exempted under the authority of 21 CFR 1002.50 from the requirements of 21 CFR 1002.10, 1002.11, 1002.12, 1002.30 and 1002.31 provided that such person notifies the Director, Division of Compliance, that less than 10 sunlamp products are being manufactured for the use of that person and provides the Director with the name and address of the manufacturing location.

Persons who wish to manufacture more than 10 sunlamp products for use in their own commercial suntanning facilities are not included in this exemption but may make a written application for exemption to the Director, Bureau of Radiological Health, in accordance with 21 CFR 1002.50 stating the number of products they intend to manufacture and over what period of time manufacturing will occur.

John C. Villforth
Director
Bureau of Radiological Health