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Statement To The Technical Electronic Product Radiation Safety Standards Committee Regarding the Food and Drug Administration's proposed amendments to the U.S. performance standards for sunlamp products, 21 CFR 1040.20, and certain initiatives of international standards organizations concerning sunlamp products.

Submitted by:

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I am submitting this statement to the Committee in response to the anticipated recommendations by the Food and Drug Administration regarding proposed amendments to the U.S. performance standards for sunlamp products, 21 CFR 1040.20. Due to the time constraints of the Committee, I will not be speaking on all proposed changes. However, I would like to make several comments related to some of the proposals.

1. Warning Label Inclusion on all Promotional Material

Although I agree on the importance of consumer-based warning labels on any product that has the potential to cause harm if used improperly, I would remind the Committee to consider the principal intended target of a warning label on a tanning device. This label is primarily intended for the consumer using the device for tanning purposes.

The primary function of any warning label is to protect those who are least able to protect themselves: in this case, the tanning consumer. People most likely to misuse a product are not typically those who are about to invest from $2,500 for a single unit to $250,000 for the opening of a new tanning salon. These individuals have researched the market, compared products, tested equipment in a salon setting and have most likely participated in one of three nationally recognized indoor tanning certification programs that routinely cover the adverse affects caused by the misuse of a tanning device.

To require a legible reproduction of the warning statement required by 21 CFR 1040.20(d)(1)(I) to all catalogs, specification sheets and descriptive brochures, and any other purchasing information pertaining to each sunlamp product and ultraviolet lamp is overkill. Let's keep the warning label on the equipment so intended users can have access to this information and, at most, include a reproduction of the label in the operator's manual where it makes sense.

Let's ask this question: What is a label suppose to achieve? It is suppose to create awareness and education. Research has shown that warning labels are most effective when it offers new information that is believable and that is targeted to the intended audience at an appropriate time [1].

As executive editor of LOOKING FIT magazine, an indoor tanning trade publication, I can attest to the fact that warning labels within promotional advertising in publications like ours or within informational brochures is not only ineffective, it can also be financially restrictive to some companies.

2. Redefining a Manufacturer

The proposal that "any person engaged in the business of manufacturing, assembling, or modifying sunlamp products shall be construed as manufacturing under the act if the modification affects **any** aspect of the product's performance or intended function(s)" be deemed a manufacturer could be detrimental to the

daily activities of more than 60,000 legitimate businesses offering commercial indoor tanning services.

The FDA's revision for the definition of a manufacturer should be considered very carefully. Currently, most salon owners maintain and repair equipment themselves. Occasionally, maintenance or repairs go from routine to complex.

The definition of a manufacturer must be detailed.

Even in aircraft maintenance, there are two definitions of "modification" during routine or major repairs:

Minor Modification-means type design changes made to an aircraft, including its components or items of equipment and their installation, or the substitution of one type of installed component or equipment for another.

Major Modification-a design change not listed in the original equipment specifications. These are things that affect structural strength, or other qualities affecting operational or environmental characteristics as well as any modification that would be considered "Non-standard" operational procedures.

Prior to redefining a manufacturer we must clearly define repairs or modifications that do not "significantly" affect the structural integrity or intended output of a tanning device. This can be accomplished by working closely with manufacturers as well as salon owners who routinely service and repair their equipment. For a salon owner to unwittingly cross the line on manufacturer status would be a financial disaster from which most could not recover.

Conclusion

The ultimate goal of federal, state and local regulatory agencies is to protect the consumer. As the indoor tanning industry grows across the country, these same agencies are stretched to the limit in carrying out that primary objective. With this in mind, it is ultimately the responsibility of indoor tanning facilities to assure that mandatory regulations as well as sound facility practices are being followed in day-to-day operations—with the health and safety of the tanning consumer utmost in mind.

Considering the common goals among agencies and industry, it is my wish that both groups work jointly in developing and defining objectives that have the needs of the tanning consumer in mind.

I appreciate the opportunity to submit this statement to the Committee. I hope that this statement and my future submissions and interactions will assist the Committee in their work on these important topics.

1 Ayres, T.J.; Gross M.M.; Wood, C.T.; Horst, D.P.; Beyer, R. R.; and J.N. Robinson. 1989. What is a warning and when will it work? In *Proceedings of the Human Factors 33rd Annual Meeting*.