

- c) Explain whether the minimal erythral dose (MED) of 1 J/cm² is intended to be a weighted or unweighted dose, or how this value (1 J/cm²) was determined.

Comment

The MED for pre-irradiation in the April 9, 1996 CTFA data was 1 J/cm², unweighted. This "dose" of UV was based loosely on the MEDs obtained in 142 subjects with Skin Types I and II (presented in Fig. 2, Appendix II, April 9, 1996 FDA submission, Docket 78N-0038, from CTFA⁴). At the time, this value was considered a reasonable pre-irradiation dose. However, we consider the 1 J/cm² dose as too low an estimate of MED.

We believe a dose of 2 J/cm² is a more accurate estimate of an MED. This is based on the work by Lavker *et al.*⁷. In these studies, it was experimentally determined that one MED in mostly Fitzpatrick Skin Type II individuals was 2 J/cm² delivered from a 150 W xenon arc solar simulator, equipped with a 1 mm WG-320 and 1 mm UG-5 filters. Therefore, we advocate the use of 2 J/cm², unweighted, as a dose equal to 1 MED from a full spectrum solar simulator.

It should be understood that the intent of the pre-irradiation dose of UV is to mimic the conditions a consumer might experience while using a sunscreen product. Specifically, consumers apply sunscreen products to be protected against *solar UV*. As such, an unweighted dose of solar simulated UV (i.e., 290-400 nm) is recommended. As well, we believe the pre-irradiation dose should be adjusted for SPF. This would ensure that sunscreen products are tested at a sufficient but not an unreasonable dose of solar-simulated UV. *A more complete comment regarding the pre-irradiation dose of UV is presented on page 17 of this document in response to question 4(d).*

⁷ Lavker, RM, Gerberick, FG, Veres, D, Irwin, CJ, Kaidbey, KH (1995) Cumulative effects from repeated exposures to suberythral doses of UVB and UVA in human skin. *J Am Acad Dermatol* 32:53-62.