3. INFORMATION REGARDING YOUR[6] "CRITICAL WAVELENGTH" METHOD SUBMISSION (FROM THE ABOVE MENTIONED JULY 16TH LETTER):

a) It was stated that "a region of the substrate at least 1 cm^2 in area will be measured (spectrometer)" or "5 individual regions of the substrate at least 0.25 cm^2 in area will be measured (spectroradiometer)." Explain why the difference in instrumentation choice would influence the number of measurements taken or the size of the area measured.

Comment

Generally speaking, an attempt is made to measure a relatively large surface area to account for any non-uniformity in product application to the substrate. As a guideline, it is recommended that *". . . a region of the substrate at least 1cm^2 be measured . . ."*. For any given instrument, the area that can be measured may differ. For example, an individual measurement from a standard spectroradiometer could be 0.25 cm^2 and therefore, at a minimum, 4 individual regions of the substrate should be measured to comply with the guideline (i.e., 0.25 cm^2 x 4 individual areas = 1 cm^2 total area measured or the absolute minimum). It is possible that another instrument is only capable of measuring 0.10 cm^2, in which case 10 individual regions of the substrate should be measured to comply with the 1 cm^2 guideline. Thus, although the individual areas may be different based on the equipment, the total region of the substrate measured should be equal to or greater than 1 cm^2. What is important is that a relatively large surface area of the substrate is evaluated to ensure accurate spectra measure and calculation of the critical wavelength.

[6] April 9, 1996 letter from Mr. Thomas Donegan, CTFA, to Docket No. 78N 0038, *Methodology for Evaluation of UVA Efficacy of Sunscreen Products*