



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

JUN 25 1985

TO: ALL MANUFACTURERS, IMPORTERS AND POTENTIAL MANUFACTURERS
OF SUNLAMP PRODUCTS.

SUBJECT: POLICY ON WARNING LABEL REQUIRED ON SUNLAMP PRODUCTS.

BACKGROUND:

The Center for Devices and Radiological Health has found numerous imported and domestic sunlamp products labeled in such a way as to render the label illegible and/or inaccessible to view by the consumer under normal conditions of purchase and use.

Sunlamp products are electronic products as defined by Section 355(2) [42 U.S.C 263c(2)] of the Radiation Control for Health and Safety Act of 1968 (RCHSA) and medical devices as defined by Section 201(h)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C) [21 U.S.C.321(h)(3)]. The performance standard for sunlamp products (21 CFR 1040.20) promulgated under authority of Section 358 of the RCHSA, requires that labels containing specific information be permanently affixed or inscribed on an exterior surface of the product so as to be legible and readily accessible to view when the product is fully assembled for use. The general labeling provisions for medical devices under 21 CFR 801.5 require adequate directions for use be provided to the user and 21 CFR 801.15 defines the prominence of the required label statements for devices.

POLICY:

The intended purpose of the warning label required on sunlamp products is to provide that information necessary for the consumer to make an informed decision regarding the risks of using sunlamp products and to provide adequate directions for skin tanning. Therefore, the label must be legible and conspicuously placed on the product so as to render it likely to be read by the user under normal conditions of purchase and use. The Agency will consider sunlamp products to be noncompliant with the performance standard under Section 358(a)(1) of the RCHSA and misbranded under Section 502(c) of the FD&C Act if the required product label is not legible and accessible to view for the following reasons:

1. The label required under 21 CFR 1040.20(d)(1) does not appear on a prominent part or panel which is presented or displayed under normal conditions of purchase and/or use.
2. Adequate space is not provided for the required label or the label is not prominently displayed on the device.
3. The normal individual can not read the label from a distance of one meter because of inadequate lettering size and background contrast. Lettering of ten (10) millimeters (height) for the word "DANGER" and five (5) millimeters for the rest of the label information is recommended to meet the visibility requirements.



Walter E. Gundaker, Director
Office of Compliance
Center for Devices
and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 21 1986

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

TO: ALL MANUFACTURERS, IMPORTERS AND POTENTIAL MANUFACTURERS OF
SUNLAMP PRODUCTS.

SUBJECT: POLICY ON MAXIMUM TIMER INTERVAL AND EXPOSURE SCHEDULE FOR
SUNLAMP PRODUCTS.

BACKGROUND:

The amended performance standard for sunlamp products (21 CFR 1040.20) was published in the September 6, 1985 issue of the Federal Register and will become effective September 8, 1986. Any sunlamp product manufactured on or after that date must comply with the amended standard.

The ten (10) minute maximum timer interval requirement was removed from the original performance standard since there are newer sunlamp products on the market for which ten (10) minutes is not appropriate. The maximum timer interval now depends on the intensity and spectral distribution of ultraviolet (UV) radiation emission of each individual model of sunlamp product and must not exceed the maximum recommended exposure time provided on the required product warning label. Therefore, sunlamp product manufacturers must develop an exposure schedule and establish the maximum recommended exposure time (and therefore the maximum timer interval) based on the characteristics of their particular products.

The intended purposes of a sunlamp product timer are to provide for reliable control of exposures and to limit acute (and delayed) damage from unintentionally long exposures. However, the maximum timer setting should also allow for selection of exposure times needed to build up and maintain a tan. The maximum timer interval is in no way to be considered as a safe limit; all ultraviolet radiation is potentially hazardous.

The standard requires the manufacturer to provide an exposure schedule in the product warning label. The purpose of the exposure schedule is to allow a person to gradually build-up skin pigmentation and to maintain a tan while controlling the risk of acute injury and delayed adverse effects. Since the UV radiation dose that causes a barely discernible pink coloration (minimal erythema dose or MED) is not the same for different skin types, the exposure schedule for first time users will depend on the skin type of the user. Furthermore, suberythemogenic doses of UV radiation received at 24 hours intervals initially lead to lowering of the erythema and tanning thresholds. Therefore, the exposure schedule and maximum recommended exposure time should be constrained by the potential for erythema as well as the quantity of radiation necessary to achieve and maintain a tan.

POLICY:

The Center for Devices and Radiological Health (CDRH) will use the following criteria to evaluate the adequacy of the exposure schedule and the recommended maximum exposure time (and therefore the maximum timer interval):

1) The maximum recommended exposure time (and maximum timer interval) must not exceed a value which will result in an exposure of four (4) times the minimal erythema dose (MED) for untanned Type II skin (always burns, then tans slightly). This is based on the CDRH Erythema Action Spectrum [proposed action spectrum of Commission Internationale de L'Eclairage (CIE) modified by CDRH]. See Appendix A for the action spectrum and weighting factors and equations needed to derive it.

The formula for determining the recommended maximum exposure time, "T_e" in seconds is:

$$T_e = \frac{624J/M^2}{\sum V_i R_i} \quad \text{where Standard MED} = 156J/M^2 \text{ at } 296nm$$

V_i = weighting factor
 R_i = irradiance in W/M²

2) The recommended maximum exposure time must not exceed a value which will result in an exposure of four (4) times the minimal melanogenic dose (MMD) for untanned Type II skin. This is based on the melanogenic action spectrum developed by Parrish et al (1982). See Appendix B for this action spectrum.

The formula for determining the recommended maximum exposure time, "T_m" in seconds is:

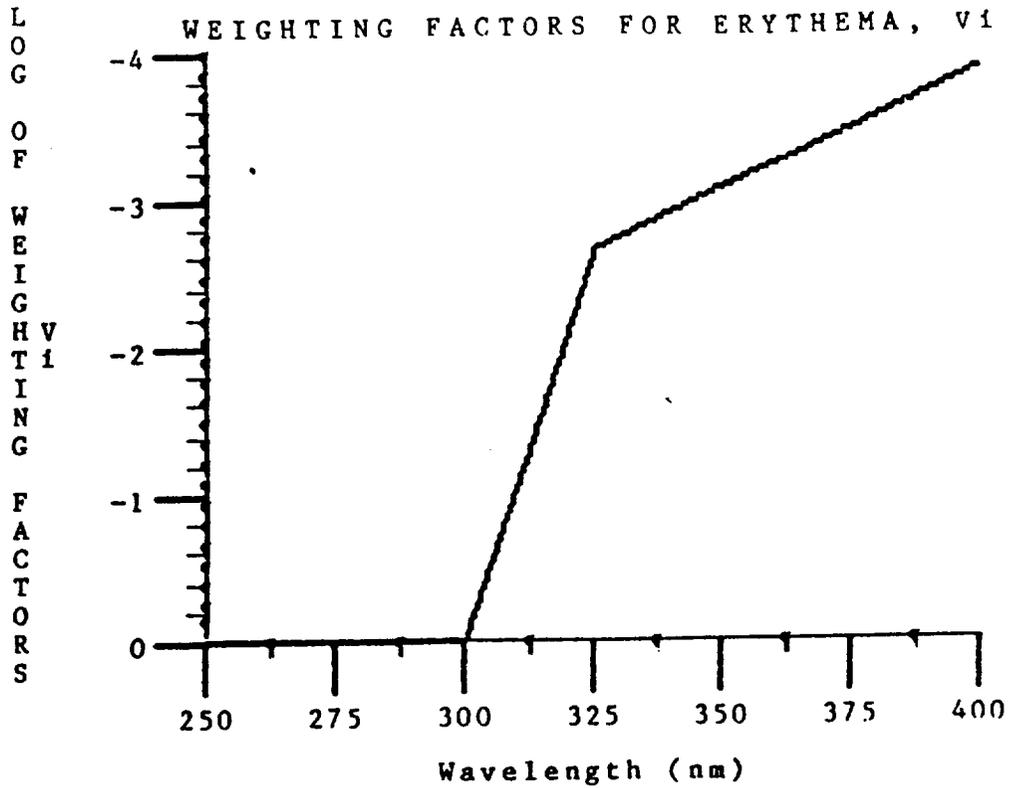
$$T_m = \frac{1836J/M^2}{\sum J_i R_i} \quad \text{where standard MMD} = 459J/M^2 \text{ at } 296nm$$

J_i = weighting factor
 R_i = irradiance in W/M²

3) The recommended exposure schedule should provide for exposures of no more than 0.75 MED three times the first week, gradually increasing the exposure the following weeks until maximum tanning has occurred (approximately four weeks total) and then provide for maintenance of a tan by biweekly or weekly exposures of up to four(4) MEDs or four(4) MMDs, whichever is less.

CDRH believes that the above criteria balances the need to limit acute (and delayed) damages from unintentionally long exposure and the need to provide for single exposure durations adequate to achieve and maintain a tan.

for Ann B. Hall
Walter E. Gundaker, Director
Office of Compliance
Center for Devices and
Radiological Health



The equations describing the curve are:

$$v_1(\lambda) = 1.0 \quad (250 < \lambda < 302 \text{ nm})$$

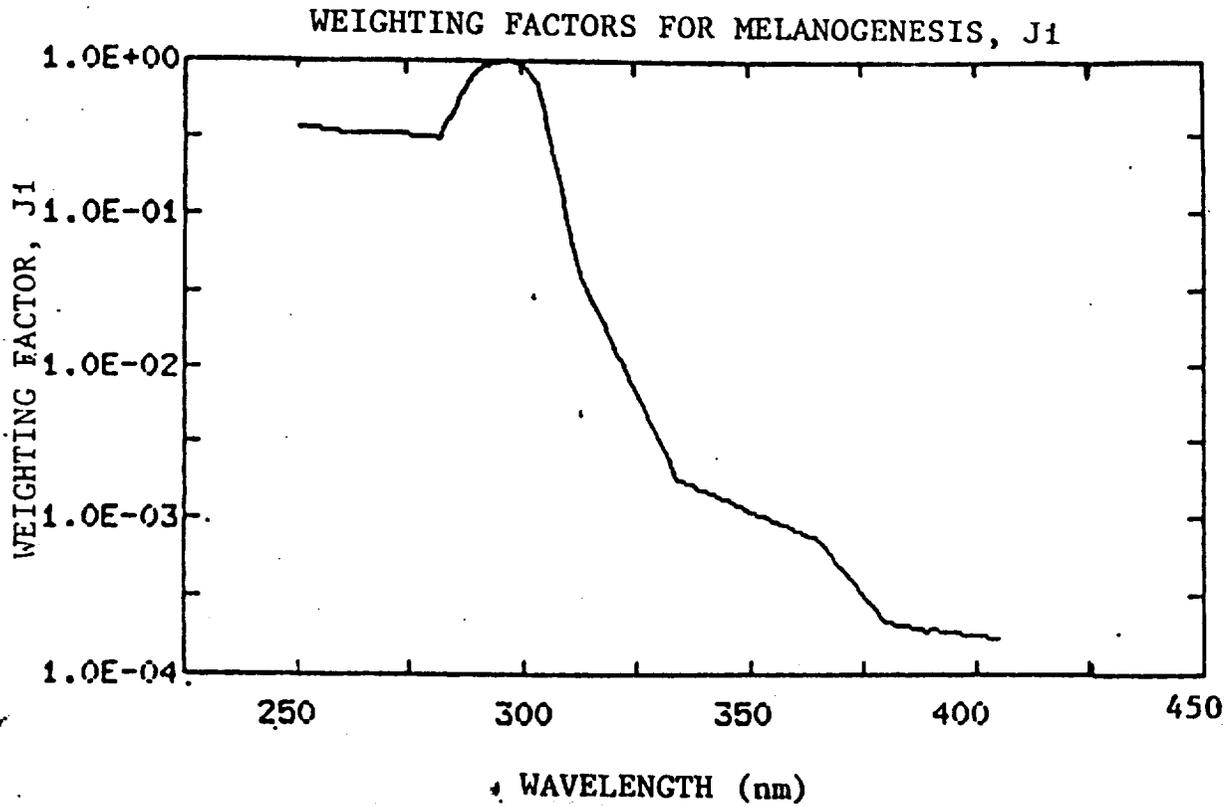
$$v_1(\lambda) = 10^{0.114(302-\lambda)} \quad (302 < \lambda < 325 \text{ nm})$$

$$v_1(\lambda) = 10^{0.0161(159-\lambda)} \quad (325 < \lambda < 405 \text{ nm})$$

DRAFT

[DATA]GIELTYLE ERYTHEMA, Vi
CIE ACTION SPECTRUM MODIFIED BY LYTLE (CDRH) NORMALIZED TO 1 AT
250-302 NLIMIT IS 156 J/M2

WAVELENGTH	READING				
250	1	306	.3499	362	.539122E-03
251	1	307	.2692	363	.519508E-03
252	1	308	.207	364	.500607E-03
253	1	309	.1592	365	.482395E-03
254	1	310	.1225	366	.464844E-03
255	1	311	.09419	367	.447931E-03
256	1	312	.724399E-01	368	.431636E-03
257	1	313	.557199E-01	369	.415931E-03
258	1	314	.428499E-01	370	.4008E-03
259	1	315	.03296	371	.386207E-03
260	1	316	.253499E-01	372	.372145E-03
261	1	317	.0195	373	.358596E-03
262	1	318	.01499	374	.345538E-03
263	1	319	.01153	375	.332958E-03
264	1	320	.887199E-02	376	.320835E-03
265	1	321	.682299E-02	377	.309154E-03
266	1	322	.005248	378	.297898E-03
267	1	323	.004036	379	.287051E-03
268	1	324	.310499E-02	380	.276601E-03
269	1	325	.212499E-02	381	.26653E-03
270	1	326	.204778E-02	382	.256828E-03
271	1	327	.197338E-02	383	.247479E-03
272	1	328	.190168E-02	384	.238469E-03
273	1	329	.183259E-02	385	.229789E-03
274	1	330	.176601E-02	386	.221424E-03
275	1	331	.170178E-02	387	.213363E-03
276	1	332	.168981E-02	388	.205596E-03
277	1	333	.158014E-02	389	.198112E-03
278	1	334	.152263E-02	390	.1909E-03
279	1	335	.146723E-02	391	.183956E-03
280	1	336	.141383E-02	392	.177267E-03
281	1	337	.136238E-02	393	.170821E-03
282	1	338	.131281E-02	394	.164608E-03
283	1	339	.126503E-02	395	.158621E-03
284	1	340	.001219	396	.152852E-03
285	1	341	.117461E-02	397	.147293E-03
286	1	342	.113183E-02	398	.141936E-03
287	1	343	.109062E-02	399	.136774E-03
288	1	344	.10509E-02	400	.1318E-03
289	1	345	.101263E-02	9999.9	1
290	1	346	.975755E-03		
291	1	347	.940221E-03		
292	1	348	.905983E-03		
293	1	349	.87299E-03		
294	1	350	.841199E-03		
295	1	351	.810582E-03		
296	1	352	.781079E-03		
297	1	353	.752649E-03		
298	1	354	.725254E-03		
299	1	355	.698856E-03		
300	1	356	.678419E-03		
301	1	357	.649909E-03		
302	1	358	.62529E-03		
303	.7691	359	.60253E-03		
304	.5916	360	.5806E-03		
305	.455	361	.559477E-03		



The MMD as function of wavelength has been interpolated (using log MMD) from the action spectrum for melanogenesis of type II skin (Parrish et al 1982)

PARRISH MELANOGENESIS TYPE II SKIN 1982 NORMALIZED TO 296 NM

WAVELENGTH (nm)	Ji				
250	.378409	302	.815892	354	.100202E-02
251	.374828	303	.750391	355	.972644E-03
252	.371248	304	.690261	356	.944186E-03
253	.367714	305	.502296	357	.916645E-03
254	.364225	306	.36551	358	.890022E-03
255	.360783	307	.265997	359	.863859E-03
256	.35734	308	.193565	360	.838613E-03
257	.353943	309	.14087	361	.813826E-03
258	.350547	310	.102497	362	.789958E-03
259	.347196	311	.745893E-01	363	.767007E-03
260	.343891	312	.054301	364	.747729E-03
261	.340632	313	.395016E-01	365	.722942E-03
262	.337419	314	.341137E-01	366	.666943E-03
263	.334206	315	.294593E-01	367	.615075E-03
264	.331039	316	.254384E-01	368	.567338E-03
265	.327672	317	.219683E-01	369	.523272E-03
266	.327413	318	.189709E-01	370	.48288E-03
267	.326954	319	.163821E-01	371	.44547E-03
268	.326449	320	.141467E-01	372	.410953E-03
269	.32599	321	.122143E-01	373	.379097E-03
270	.325531	322	.105481E-01	374	.34972E-03
271	.325072	323	.911137E-02	375	.322593E-03
272	.324613	324	.786745E-02	376	.297577E-03
273	.324154	325	.679336E-02	377	.274534E-03
274	.323695	326	.586616E-02	378	.253236E-03
275	.323236	327	.506748E-02	379	.233591E-03
276	.321445	328	.437483E-02	380	.215506E-03
277	.319609	329	.377812E-02	381	.213532E-03
278	.317865	330	.326265E-02	382	.211558E-03
279	.316075	331	.281741E-02	383	.209963E-03
280	.314285	332	.243276E-02	384	.207702E-03
281	.312541	333	.210089E-02	385	.205821E-03
282	.31075	334	.181447E-02	386	.203939E-03
283	.351694	335	.176123E-02	387	.202057E-03
284	.398008	336	.170982E-02	388	.200221E-03
285	.450427	337	.165978E-02	389	.189296E-03
286	.509732	338	.161113E-02	390	.196594E-03
287	.576885	339	.156385E-02	391	.194804E-03
288	.652851	340	.151841E-02	392	.193014E-03
289	.738778	341	.147388E-02	393	.191224E-03
290	.836088	342	.143074E-02	394	.18948E-03
291	.861518	343	.138897E-02	395	.187735E-03
292	.887498	344	.134812E-02	396	.186037E-03
293	.91435	345	.130864E-02	397	.184339E-03
294	.94212	346	.127054E-02	398	.18264E-03
295	.970625	347	.123336E-02	399	.180988E-03
296	1	348	.11971E-02	400	.179336E-03
297	.990959	349	.116222E-02	401	.177683E-03
298	.982054	350	.112825E-02	402	.176077E-03
299	.973287	351	.10952E-02	403	.17447E-03
300	.96429	352	.106307E-02	404	.172864E-03
301	.886993	353	.103232E-02	405	.171257E-03