DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

AUG 21 1986

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 erythemal 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:

$$T_e = \frac{624 J/M^2}{\sum V_i R_i}$$

where Standard MED = $156 J/M^2$ at 296nm
$V_i$ = weighting factor
$R_i$ = irradiance in $W/M^2$

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:

$$T_m = \frac{1836 J/M^2}{\sum J_i R_i}$$

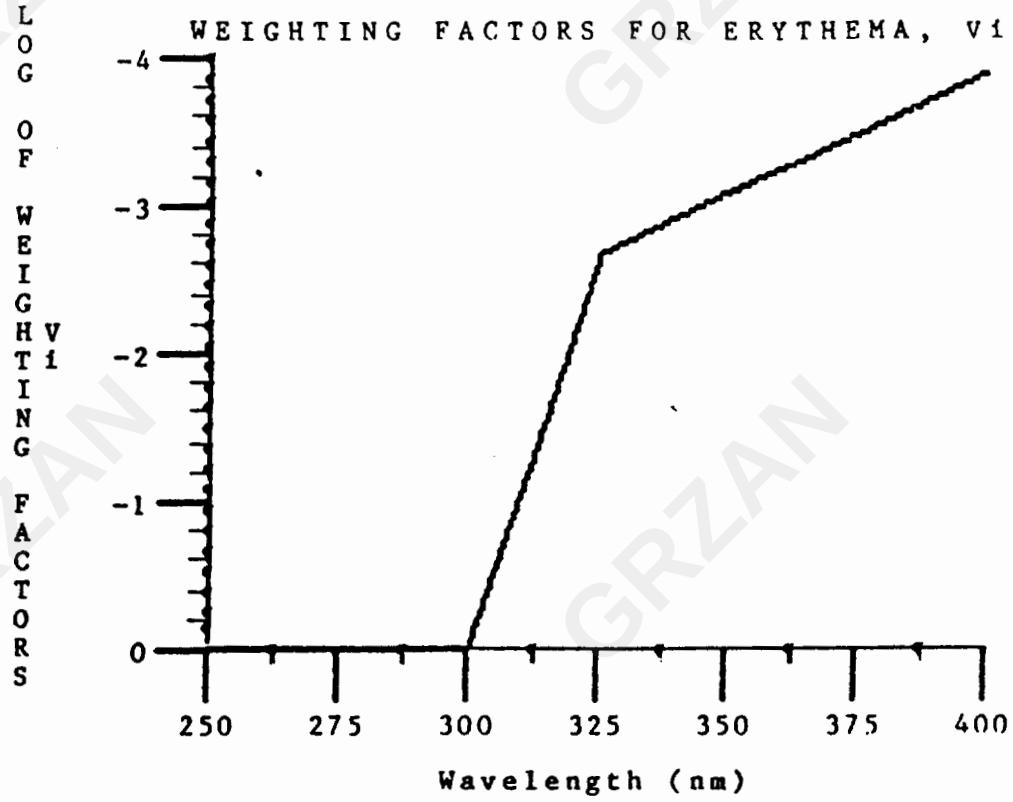
where standard MMD = $459 J/M^2$ at 296nm
$J_i$ = weighting factor
$R_i$ = irradiance in $W/M^2$

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.

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

Appendices




**The equations describing the curve are:**

$V_i(\lambda)=1.0$ $(250 < \lambda < 302$ nm)

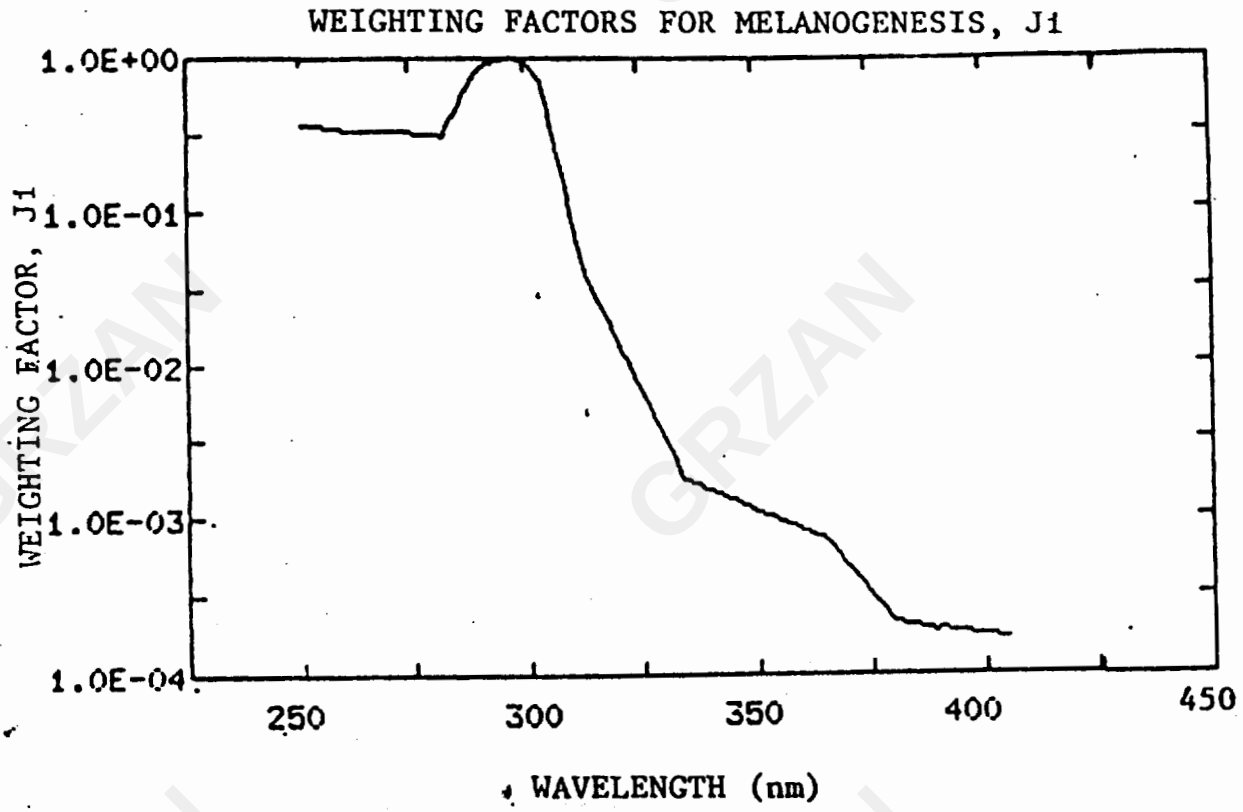
$V_i(\lambda)=10^{0.114\ (302-\lambda)}$ $(302 < \lambda < 325$ nm)

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

DRAFT

[DATA]GIELYTLE 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 | .752649-03 | | |
| 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 MELANOGENSIS 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 |