Sunlamps: Regulatory Issues

W. Howard Cyr, Ph.D.
Office of Science and Technology, Center for Devices and Radiological Health, Food and Drug Administration, Rockville, MD USA

For distribution at the following meetings:

April 2, 2001 – 2nd Annual Indoor Tanning Regulatory Conference, Phoenix, AZ

May 17, 2001 - Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC)

W. Howard Cyr, Ph.D.
12709 Twinbrook Parkway
Rockville, MD 20852 USA
Tel: (301) 443-7179
Fax: (301) 594 6775
Hwc@cdrh.fda.gov
Howard@cyr.net

NOTICE

This summary contains background sections that are a condensed version of another, longer article to be published later this year. Some sections describing the indoor tanning industry and sources of relevant information on that industry have been omitted. Therefore, references do not start with number 1.

Additional sections, describing TEPRSSC meetings, industry-FDA meetings and other upcoming important meetings have been added.

Update for the May 17, 2001 TEPRSSC meeting

Last year, we presented five possible changes to the FDA Performance Standard for Sunlamp Products. This presentation came after a review of comments that were obtained as a result of our publishing an Advanced Notice of Proposed Rulemaking (ANPRM). A review of the ANPRM and comments is presented in several sections below. FDA concluded that some of the possible changes that were presented in the ANPRM needed more research data or more analysis before formal presentation before TEPRSSC. Therefore, FDA narrowed its possible specific proposals to five:

1. Establish the existing Recommended Exposure Schedule [18] as part of the Performance Standard, itself.

2. Use the human cancer action spectrum [25] in a manner similar to that used by the International Electrotechnical Commission (IEC).

3. Require those that make significant changes that affect performance of sunlamps or sunbeds to assume the responsibilities of manufacturers.

4. Require a simpler, easier-to-read warning label

5. Require warning label in catalogues, specification sheets, and manufacturer's brochures.

FDA felt that these changes would be the easiest to implement and would be relatively "uncontroversial". At last year's TEPRSSC meeting, representatives from the indoor tanning industry disagreed with FDA's proposals, suggesting that more analysis should be done before proceeding with any of these specific proposals. TEPRSSC advised FDA to meet with the affected industry to discuss these and other proposals to better understand the issues before returning to TEPRSSC with another round of possible changes to our Performance Standard for Sunlamp Products.

FDA met with members of the indoor tanning industry on September 13, 2000. Each issue was discussed in detail and a better mutual understanding of the issues was reached. However, more work is needed, and additional meetings, discussions, and workshop are anticipated to address possible specific changes to our standard. . Summaries of the proceedings of the September 13, 2000 meeting have been written by the industry trade journals and several industry-related internet sites.

Therefore, it is premature for FDA to present specific changes at this year's 2001 meeting of TEPRSSC. Instead, we will present this written summary of our activities with the indoor tanning industry and other organizations. In addition, we will summarize our plans for future work with industry, academia, medical community, and general public with regards to possible amendments to the Performance Standard for Sunlamps Products. We are open to questions and discussion about this Progress Report.

The future

The FDA will continue to evaluate the numerous responses it has received from the ANPRM and from subsequent meetings with the medical community and the indoor tanning industry. After a complete assessment, FDA will propose specific amendments to its current performance standard. These amendments will be based on the current best science of the documented bioeffects of UV. These amendments will bring the current regulations up-to-date. However, the regulatory process is never static. The new amendments will, in turn, also be subject to change as a better understanding of the science of UV effects and better assessments of the risks associated with UV exposures from sunlamps are developed.

List of upcoming important meetings at which pertinent issues will be discussed

April 13, 2001 – **2nd Annual Indoor Tanning Regulatory Conference,** Phoenix, AZ. FDA will participate by teleconferencing, answering specific questions about regulations on sunlamps and sunbeds.

May 17, 2001 – **Technical Electronic Product Radiation Safety Standards Committee** (TEPRSSC) meeting in Maryland to discuss any new proposed rules for radiation-emitting products. **NO** proposed rules will be presented at this year's TEPRSSC meeting. This written summary will be presented to TEPRSSC.

June 7 and 8, NIH campus, Bethesda, MD – meeting of the **National Council on Skin Cancer Prevention (June 7) and the Federal Council on Skin Cancer Prevention (June 8).** The former is composed of medical, academic, and other non-government organizations dealing with skin cancer. The latter is composed of government agencies dealing with the same issues. UV-related skin cancers are a common topic. Reviews of research, regulations and educational efforts are presented. This Council's main emphasis is on methods, such as education efforts, to teach workers and the general public about the different types of skin cancer and ways to prevent them.

June 9 – 12, 2001 **Effects of Light**, Boston, MA
http://www.bioeffectsoflight.org/2001symp.html FDA will participate in this meeting and will give results from its research effort on methods to measure changes in human skin following UV exposures.

July 7-12, 2001 – **29th Annual Meeting, American Society for Photobiology**, Chicago, IL
http://www.pol-us.net/ASP_Home/Meetings/Annual2001/29asp00.html
Two sessions will be of particular interest – on Saturday July 7, there will be a session on "Burning, Tanning and Typing" headed by Dr. Janusz Beer of CDRH.
On Sunday, July 8, there will be a session on "Optimizing Exposure Schedules and Sources" headed by Sharon Miller and Howard Cyr, both of CDRH. The schedule of speakers is available at the above web site.

September 3-8: **9th European Society for Photobiology**, Lillehammer, Norway
http://esp.nrpa.no
Special session on indoor tanning. At this time, there is no planned participation by FDA.

FDA-industry workshop on lamp compatibility - This meeting is in the planning stages only.

The remainder of this paper gives background information that has already been presented to TEPRSSC. It is presented here as a reference. It is also presented for others who may not be familiar with the history of the Advanced Notice of Proposed Rulemaking in which FDA asked for data and comments on possible changes to FDA Performance Standard for Sunlamp Products

Background

The medical community has long advocated that sunlamps be banned for all but medical purposes. They maintain that sunlamps create significant health risks and provide no benefit other than a cosmetic tan [17]. Others, including the US Food and Drug Administration (FDA), concluded that the hazards from sunlamps are similar to those from solar UV exposures, which are common and difficult to control. A person who exposes him or herself to the sun will get ultraviolet radiation similar to that from a sunlamp (less UVB, more UVA), but there could be an increased risk of sunburn. FDA decided to regulate sunlamps with a performance standard "to protect the consumer from acute burns (as evidenced by erythema) and from exposure to hazardous radiation that is unnecessary for skin tanning [18]".

The performance standard also includes a provision "to warn the consumer of the known adverse effects to the body after exposures to ultraviolet radiation"[19]. In addition, the standard also "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 injuries and delayed adverse effects [18].

The performance standard of 1986 [19] and the policy letter of 1986 [18] have remained in effect with no changes until now. Recently, the FDA has considered some possible changes to these regulations and recommendations as a result of both FDA's re-assessments and requests from the medical community and concerned citizens. These possible changes will be discussed in a later section.

Existing US Regulations

The Food and Drug Administration published a performance standard for sunlamps and sunlamp products on November 9, 1979 and it became effective on May 7, 1980. A revised standard was published on September 6, 1985 and became effective one year later on September 8, 1986 [19]. There are no requirements for pre-market clearance for sale of sunlamps or sunbeds that are used for cosmetic purposes. Most of FDA's regulation of sunlamps occurs through the review of product reports from the manufacturers, periodic inspections of manufacturers, and FDA field office inspections of salons.

The FDA regulations on sunlamps and sunlamp products can be found in 21 CFR 1040.20 (Chapter 21 of the Code of Federal Regulations, Part 1040.20, and also at the following web site: http://www.fda.gov/cdrh/radhlth/index.html (Select "sunlamp products for all standards and reporting guides, etc.)

State regulations

FDA cooperates with many state governments to provide training programs for state and local inspectors of tanning facilities. The FDA and several states also have joined together with the Conference of Radiation Control Program Directors (CRCPD) to develop a model ordinances that can be used by the various state or local governments ("Suggested State Regulation for Control of Radiation, Part BB for tanning facilities"). One can obtain a copy of this suggested regulation from CRCPD at: http://www.crcpd.org. One can contact the various state radiation control programs that regulate sunlamps by selecting "**State Programs"** at the above web site with linkage to the various states: http://www.crcpd.org/links.htm

International Electrotechnical Commission (IEC) and Commission Internationale d'Eclairage (CIE)

One of the FDA's goals in recent years is to harmonize its standards with those of other countries, and if possible, to make the U.S. standards compatible or identical to international standards. The U.S. Congress mandated this harmonization effort when it passed the 1997 Food and Drug Modernization Act (FDAMA)[20]. To accomplish this goal, FDA has participated in the development of standards related to UV radiation and sunlamps written by the Commission Internationale d'Eclairage (CIE) and the International Electrotechnical Commission (IEC). The CDRH has representatives to both of these international organizations.

http://www.iec.ch/

National Toxicology Program

The National Toxicology Program (NTP) is part of the National Institute of Environmental Sciences within the National Institutes of Health. This December 2000 participants at the NTP meeting discussed a nomination to include Broad Spectrum Ultraviolet (UV) Radiation and UVA, and UVB, and UVC on its list of known human carcinogens. The background document for this nomination can be found on the NTP web site: http://ntp-server.niehs.nih.gov/ (Click on "What's new" in the upper left corner. Scroll down to "Report on Carcinogens – Background Sunlamps are in part 3.2 of that document.)

Federal Council for Skin Cancer Prevention

Government agencies interested in skin cancer, and in particular, skin cancer caused by UV radiation meet on at biannual meetings of the Federal Council for Skin Cancer Prevention. There is a parallel non-government organization called the National Council for Skin Cancer Prevention. Representatives to the Federal Council from the numerous government agencies discuss methods to prevent skin cancer and discuss scientific issues relating to UV-caused skin cancer. One recent meeting included discussion of NTP's listing of sunlamps as a known human carcinogen. The Federal Council for Skin Cancer Prevention has a web site at:

http://www.cdc.gov/cancer/linksalt.htm#skin

FDA is considering amendments to its Performance Standard for Sunlamp Products

In 1994, FDA received a request from the U.S. American Academy of Dermatology (AAD) and the American Medical Association (AMA) to ban sunlamps. This action was prompted, in part, by a Swedish study on melanoma incidence among users of sunlamps. This study by Westerdahl et al. [11] concluded that persons who had used sunlamps were at an increased risk of malignant melanoma. The FDA reviewed this and other studies and concluded that the data was – "suggestive, but not conclusive" of an association between malignant melanoma and sunlamp usage. FDA told the AMA and AAD that it would continue to monitor the scientific literature, and if new data became available, FDA would reconsider its position. In 1995, FDA received a petition from an U.S. citizen who requested that FDA make several changes in its regulations regarding to sunlamps and sunlamp.

In response to these various requests/petitions and to an analysis of its regulations, FDA decided to consider some changes to existing regulations. On February 9, 1999, FDA published an Advanced Notice of Proposed Rulemaking (ANPRM)[21] asking for comments and data on possible changes to the Sunlamp Performance Standard.

Four reasons why FDA published an Advanced Notice of Proposed Rulemaking on Possible changes its Sunlamp Products Performance Standard

There were four major issues that led the FDA to issue its ANPRM. In the United States, melanoma has been increasing at an alarming rate, and dermatologists attribute this increase to lifestyle changes, in which individuals in this century have exposed more of their bodies, more frequently to intense sunlight, and more recently, to UV exposures from tanning lamps. This increase in the incidence of melanoma is alarming because melanoma has a high fatality rate. This is in contrast to basal and squamous cell carcinomas, which are quite curable, if diagnosed early and treated. There were also published reports of epidemiological studies linking exposure to sunlamps with increased melanomas [12][13][22][23], and reports that UVA, a main component of sunlamps, was more effective in inducing melanoma than in inducing erythema [24]. These studies received considerable attention in the scientific/medical community and prompted the dermatologists, in particular, to solicit the FDA to ban sunlamps for all purposes other than medical treatment. Should the FDA chose not to ban sunlamps, the dermatologists advised FDA take stronger actions to warn the public about possible increased dangers from exposures to sunlamps. The public health concern about increases in malignant melanoma and a possible linkage to tanning lamps were the chief driving forces behind FDA's efforts to re-evaluate the scientific data and to investigate whether FDA warning labels and recommended exposure schedules were still adequate.

The second important reason for issuing the ANPRM was the evidence that some tanning salons were not following the instructions on the warning labels and were not using exposure schedules as recommended in the FDA Policy Letter of 1986 [18]. The sale of "unlimited" tanning

sessions caused FDA concern, as did the lack of proper warnings to clients, and the increased sale of home units, which could be used in an uncontrolled environment. FDA realized that this negligence was not universal and that many salons operate in a responsible manner by heeding warning labels and following recommended exposure schedules. However, there was enough evidence from FDA inspectors to indicate that some clients may not be properly warned or may be overexposed. Therefore, in the ANPRM, FDA suggested that the current recommended exposure schedule, or a new exposure schedule based on new scientific data is added to the Sunlamp Performance Standard itself. Inclusion of a recommended exposure schedule in the Performance Standard should strengthen the regulatory authority of states and local jurisdictions in dealing with those who disregard the safety of their clients.

The third reason for issuing the ANPRM was to ask for comments on newer UV lamps and tanning beds. One specific question dealt with replacement of older lamps that may no longer be manufactured, with newer lamps. FDA also asked for comments about the re-certification of sunlamp systems, and wanted to clarify that anyone who re-certifies a sunbed system is viewed by the FDA as a manufacturer and assumes the legal responsibilities of a manufacturer.

The fourth reason for the ANPRM was to obtain comments about FDA's efforts to harmonize its requirements with those of international standards, as recommended by the FDA Modernization Act of 1997. Following an existing national or international consensus standard that FDA recognizes can simplify the regulatory notification process required by FDA before marketing of products. In particular, FDA was seeking advice on the use of standards such as those developed by the International Electrotechnical Commission (IEC).

Possible Amendments to FDA's Performance Standard for Sunlamp Products

The ANPRM asked for comments and data on:

- Incorporation of an exposure schedule into the standard. The schedule would be consistent with an accurate assessment of risks and would consider skin type, degree of previous tan, and interval between tanning sessions. A revised value of minimal erythemal dose (MED) will be part of this exposure schedule, changing the 1986 FDA value of 156 kJ/m^2 to a value currently accepted by the CIE (200 kJ/m^2 to 250 kJ/m^2).

- The use of the **S**kin **C**ancer action spectrum that was developed in **U**trecht, the Netherlands and in **P**hiladelphia and modified for **h**umans (SCUPh)[25]. The SCUPh action spectrum could be used to compute a maximum yearly UV dose for tanners, in a manner consistent with the IEC.

- Revised warning labels that are easier to read than the current detailed warning label that is required by the FDA standard. FDA proposed that there be a warning that melanoma might be possible consequence of exposure to sunlamps. After consultation with industry representatives and with scientists at major scientific meeting held in Gaithersburg, MD [26] and Bethesda, MD [27], FDA retreated from requiring a warning for melanoma, and kept the more general warning of "skin cancer", or "skin cancer (sometimes fatal)".

- A new requirement that the warning label be incorporated as part of any manufacturer's catalogue, specifications sheets and brochures.

- Clarification that anyone who re-certifies a sunbed system is viewed by the FDA as a manufacturer and assumes the legal responsibilities of a manufacturer. This means that anyone who substantially changes the performance characteristics of sunlamp or sunbed is, by definition, a manufacturer. For example, anyone who replaces lamps with non-compatible lamps assumes the responsibilities of a manufacturer.

- An easier system for determining whether a lamp is a suitable replacement for existing lamps within a sunbed. Both FDA and the industry are taking steps to develop a rating system for replacement lamps.

The indoor tanning industry has asked FDA for an additional possible change:

- Better training for operators of tanning equipment. Although, training of salon operators is not part of FDA's legal responsibilities, FDA may expand its program to help train state inspectors, and may offer advice to industry-sponsored training.

Response to FDA's ANPRM

About 30 individuals and groups replied to the Advanced Notice of Proposed Rulemaking (ANPRM), including tanning salon industry representatives, individual salon owners, manufacturers of tanning lamps, several US states, members of academia, and the dermatology community. To see these comments, one can to the FDA web site (www.fda.gov). Use the "Search" function for "sunlamp" or for "98N-1170", which is the docket number for this ANPRM. One can also go to the "Dockets" site on the FDA web site and search for "98N-1170".

The American Academy of Dermatology (AAD) and the Skin Cancer Foundation (SCF) emphasized that UV from the sun or sunlamps causes skin cancer, including melanoma. Therefore, it is prudent to avoid all exposures to UV, however they did state that some of the epidemiological studies indicated that it was intense intermittent exposure, the kind that cause sunburns, that were associated most with melanoma (and basal cell carcinoma). In addition, they warned that persons of phototypes I and II almost never tanned, and the argument that it is sunburns and not tans that are responsible for melanoma doesn't apply to these phototypes because these people almost always burn. In contrast, the indoor tanning industry argued that sunburns (i.e. intermittent, intense exposures to UV) on previously untanned skin are the main cause of melanoma. They also provided data to show that tanning salons have not been conclusively associated with increases in skin cancer [14][16]. In contrast to the statement from the dermatology community, the indoor tanning industry stated that phototypes II are able to tan. However, one spokesperson for the indoor tanning industry indicated that this group could easily burn, and therefore he has broken this group into two subgroups, one more sensitive than the other. He offers an exposure schedule that addresses these two subtypes, so that they do not get "overexposed [28]".

The biggest difference between the tanning industry and the dermatologists was the issue of possible beneficial effects of tanning. The indoor tanning industry cited studies of beneficial effects from tanning that included photo protection from further sunburns, a reduced incidence of breast and prostate cancer, a reduction in osteoporosis, and control of psoriasis [29]. In contrast, the dermatologists maintained that there are no benefits from tanning, other than cosmetic changes and possible psychological feelings of well being. They stated that studies showing so-called beneficial effects are flawed, inconclusive, or overstated [17]. However, they do acknowledge that UV-produced vitamin D does have beneficial effects, but that persons can get their vitamin D in ways that do not require exposure to UV, e.g. in food supplements [30]. The American Academy of Dermatology advised FDA not to permit claims for beneficial effects from tanning [17].

References

1. Looking Fit Tanning Fact Book 2000/2001. Virgo Publishing, (March 15, 2000) Phoenix, Arizon, USA.

2. Annual Buyer's Guide, *Looking Fit*, January, 2001, Virgo Publishing, Phoenix, Arizona, USA

3. S.A. Miller, S.L. Hamilton, U.G. Wester and W.H. Cyr, An analysis of UVA emissions from sunlamps and the potential importance for melanoma, *Photochem. Photobio.l*, 68(1)(1998): 63-70.

4. International Electrotechnical Commission - IEC 335-2-27 Safety of household and similar electrical appliances, Part 2: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation (1995), Geneva, Switzerland.

5. J. McGinley, C.J. Martin and R.M. MacKie, Sunbeds in current use in Scotland: A survey of their output and patterns of use, *British J. of Dermatol* (1998): 139: 428-438.

6. S. Miller, Unpublished data.

7. S. Wittenberg, Solar radiation and the eye: A review of knowledge relevant to eye care, *Am. J. Optom. Physiol. Opt.*, 63 (1986) 676-689.

8. P. M. Farr, B. L. Diffey, The erythemal response of human skin to ultraviolet radiation, *Br. J. Dermatol.*, 113 (1985) 65-76.

9. K. H. Kraemer, H. Slor, Xeroderma pigmentosum, *Clin. Dermatol.* 2 (1984) 33-69.

10. Skin cancer and UV radiation, P. Altmeyer, K. Hoffman, M Stucker, (eds.), Springer-Verlag, Berlin, 1997.

11. D.E. Godar, M. L Swicord, L.H. Kligman, Photoaging, in: *Proceedings on Environmental UV Radiation and Health Effects,*H-J. Schopka, M. Steinmetz (eds.), BfS-ISH-Berichte, Munich-Neuherberg, 1995, pp. 123-131.

12. J. Westerdahl, H. Olsson, A. Masback, C Ingvar, N. Jonsson, L. Brandt, P.E. Jonsson, T. Moller. Use of sunbeds or sunlamps and malignant melanoma in southern Sweden *Am. J. Epidemiol.* 140 (1994) 691-699.

13. J. Westerdahl, C Ingvar, A. Masback, N. Johsson, H. Olsson, Risk of cutaneous malignant melanoma in relation to use of sunbeds: Further evidence for UV-A carcinogenicity. *Br. J. Cancer* 82 (9)(2000) 1593-1599.

14. A.J. Swerdlow and M.A. Weinstock. Do tanning lamps cause melanoma? An Epidemiologic Assessment. *J. Am. Acad. Derm.* 38 (1998) 89 – 98.

15. L. D. Marrett. Non-solar sources of ultraviolet radiation and cutaneous malignant melanoma: A review of the evidence. In: *Epidemiological Aspects of Cutanous Malignant Melanoma,* R. P. Gallagher, J. M. Elwood (eds.), Kluwer Academic Publishers, Boston, 1994, pp. 107-127.

16. International Agency for Research on Cancer (IARC). IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 55: Solar and Ultraviolet Radiation. Lyon, France, 1992.

17. D. Riegel, American Academy of Dermatology, Exhibit C16, Food and Drug Administration Dockets, 98N-1170, Rockville, Maryland, United States.
http://www.verity.fda.gov/search97cgi/s97_cgi.exe

18. Department of Health and Human Services. Food and Drug Administration. Letter from the Director, Office of Compliance, Center for Devices and Radiological Health, to all manufacurers, importers, and potential manufactures of sunlamp products. Subject: policy on maximum timer interval and exposure schedule for sunlamps products. 21 August 1986.

19. Department of Health and Human Services, Food and Drug Administration. 21 CFR Part 1040 (Docket No. 82N-0188). Sunlamp Products; Performance Standard - Final Rule. Federal Register, Vol. 50, No. 173, Friday, September 6, 1985.

20. Food and Drug Moderization Act of 1997, Section 204 of the Act, 150th Congress of the United States, Washington DC (1997), http://www.fda.gov/cdrh/modact97.pdf

21. Advanced Notice of Proposed Rulemaking (ANPRM). Comments and Data on Possible Changes to the Performance Standard for Sunlamp Products. Food and Drug Administration. Dockets, 98N-1170, Rockville, Maryland, United States.
http://www.verity.fda.gov/search97cgi/s97_cgi.exe

22. P. Autier, J-. Dore F. Lejeune, K. Koelmel, O. Geffeler, P. Hille, J-P. Cesarini, d. Leinard, A. Liabeuf, M. Joarlette, P. Chemaly, K. Hakim, A. Koeln, U. Kleeberg, Cutaneous malignant

melanoma and exposure to sunlamps or sunbeds: An EORTC Multicenter Case-Control Study in Belgium, France and Germany, *Int. J. Cancer* 58 (1994) 8-9-813.

23. S. D. Walter, L.D. Marrett, I. From, C. Hertsman, H.S. Shannon, P. Roy, The association of cutaneous malignant melanoma with the use of sunbeds and sunlamps, *Am. J. Epidemiol.* 131 (1990) 232-243.

24. R. B. Setlow, E. Grist, K. Thompson, A.D Woodhead. Wavelengths effective in induction of malignant melanoma. *Proc. Natl. Acad. Sci. USA* 90 (1993) 6666-6670.

25. F. R. De Gruijl, H.J.C.M. Sterenborg, P.D. Forbes, R.E. Davies, C. Cole, G. Kelfkens, H. Van Weelden, H. Slaper, J.C. Van der Leun. Wavelength dependence of skin cancer induction by ultraviolet

26. Measurements of Optical Radiation Hazards, D. Sliney, P. Murray, R. Phillips, (eds.) International Commission on Non-Ionizing Radiation Protection, Markl-Druck, Munchen (1998).

27. Research Workshop on Risks and Benefits of Exposure to Ultraviolet Radiation and Tanning, National Institutes of Health, Bethesda, Maryland, USA, September 16-18, 1998, http://www.nih.gov/niams/reports/ulv.html

28. D.L. Smith, Exposure Schedules, in *Looking Fit Regulatory Conference*, March 31 – April 1, 2000, Phoenix, Arizona, USA.

29. M.F. Holick, Biological effects of light: Historical and new perspectives, in *Bioligical Effects of Light 1998*, M.F. Holick, E.G. Jung (eds.), Kluwer Academic Publishers, Norwell, Massachusetts, USA, 1999, pp.11-32.

30. R.B Sollitto, K.H. Kraemer, J.J. Giovanna, Normal vitamin D levels can be maintained despite rigorous photoprotection: Six years experience with Xeroderma pigmentosum, *J. Am. Acad. Dermatol.* 37(6)(1997) 942-947.