



**Maryland State Council on Cancer Control**  
**February 23, 2016**

**Meeting Summary**

**Members in Attendance**

Kathleen Connors-Juras  
Diane Couchman  
Kevin Cullen  
Mary Garza  
Donna Gugel  
Roger Harrell  
Christine Marino  
Jed Miller  
Artie Shelton  
Yale Stenzler  
Kala Visvanathan  
Stanley Watkins  
Brock Yetso

**Members Absent**

Stephanie Cooper-Greenberg  
Catherine Fenwick  
Kim Herman  
Kevin Kelly  
Joan Mischtschuk  
Senator Anthony Muse  
William Nelson  
Jay Perman  
Paul Rothman  
Delegate Sheree Sample-Hughes

**Staff and Guests in Attendance**

Sarah Conolly Hokenmaier  
Nanyamka Hales  
Courtney Lewis  
Elizabeth Platz  
Meredith Truss

**Welcome and Review of Minutes**

The Council approved minutes from the September 25, 2015 meeting.

**Membership Update**

There are currently two seats available on the Council. There is a need for representation from Western Maryland. Dr. Cullen offered two potential candidates during the call; Council members who have contacts in Western Maryland who may be appropriate should e-mail those to Nanyamka Hales or to Dr. Watkins. The Governor is ultimately responsible for approving proposed candidates and appointing members to the Council.

**Center for Cancer Prevention and Control (CCPC) HPV Update**

Courtney Lewis discussed DHMH activities to increase the HPV vaccine coverage rate in Maryland, which focus on parent and provider interventions to address barriers. The AHEC Maryland: Human Papillomavirus Cancer & Prevention Profile was reviewed, as well as the NCI-designated Cancer Centers statement on HPV vaccination (see handouts).

The CCPC participates on a DHMH HPV Task Force, which is involved in several initiatives including:

- Developing a report card showing HPV vaccine ordering trends for Vaccines for Children (VFC) providers;
- Requiring reporting to the statewide immunization registry for VFC providers;
- Including Medicaid HPV HEDIS data in the HealthChoice Evaluation report to be published in 2016; and
- Conducting a ‘Back to School’ campaign encouraging HPV vaccination at the same time as other vaccines required for 7<sup>th</sup> grade entry. The campaign includes implementing media strategies (TV, transit ads), as well as sending letters and resources to providers encouraging them to recommend the vaccine to patients at the recommended age. Council members will be provided with these resources that can be shared with providers and partners.

### **Maryland Cancer Collaborative and Cancer Plan Update**

Meredith Truss updated the Council on activities of the Maryland Cancer Collaborative (see handout). The 2016-2020 Maryland Comprehensive Cancer Control Plan content has been approved by DHMH leadership and is currently being formatted by a graphic designer. DHMH anticipates that the Cancer Plan will be released in April 2016.

The MCC will hold its annual meeting in April or May 2016 to correspond with the release of the updated Cancer Plan, and during this meeting the MCC will select new priorities for implementation. The meeting presents an opportunity for anyone who is interested to join the MCC and volunteer to help implement the Cancer Plan.

Council members discussed the MCC Tobacco Workgroup’s survey on Maryland college campus tobacco policies. The workgroup is finalizing a report of survey findings as well as a summary of best practices in the implementation of tobacco-free campus policies, and will post these to a website and share with the Council in the coming months.

The Council discussed the availability of data on high school tobacco rates. The 2013 Maryland Youth Risk Behavior Survey (<http://phpa.dhmh.maryland.gov/ccdpc/Reports/Documents/2013%20YRBS%20Reports/2013-YRBS-Report.pdf>) and the Biennial Tobacco Study (<http://phpa.dhmh.maryland.gov/ohpetup/Documents/HG%2013-1004%20-%20PHPA%20-%20Biennial%20Tobacco%20Study%20.pdf>) provide data on youth tobacco use.

### **Cancer Conference Updates**

Nanyamka Hales reviewed evaluation results from the 2015 Cancer Conference (see handout). In reviewing suggestions for future conferences, Council members discussed the importance of presentations on how hospitals improve cancer care, both for their cancer patients and for the population in their catchment areas.

**The 2016 Cancer Conference will be held at Anne Arundel Medical Center (AAMC) on November 15, 2016.** AAMC has, once again, generously donated conference space for the Council’s use. Nanyamka Hales presented an agenda proposal on behalf of the Maryland Cancer Collaborative Steering Committee (see handout). The MCC Steering Committee proposes

combining the 2016 Cancer Conference with the MCC Annual Meeting. Reasons for this proposal include:

- Presenting an opportunity for conference attendees to join the MCC to help implement the Cancer Plan;
- Minimizing the travel burden on conference attendees (many of whom also attend the MCC annual meeting) by combining meetings;
- Providing a networking opportunity for conference attendees during the MCC meeting;
- Reducing the number of conference presenters (which has been a recurring suggestion in cancer conference evaluations).

Council members agreed to try the proposed agenda for the 2016 conference, and discussed logistics of combining the conference with the MCC meeting. There was a suggestion to have a panel of county health departments or other programs/organizations discuss how they have successfully implemented the Cancer Plan to provide examples and inspiration to attendees. This could be tied in with the MCC Cancer Plan Implementation Awards presentation during the MCC portion of the agenda, and would replace the conference best practices panel. There was also a suggestion to have a more interactive lunch, possibly including a speaker during the second half of the lunch period.

### **Maryland Cancer Registry Advisory Committee Update**

Kala Visvanathan updated the Council on the activities of the Maryland Cancer Registry Advisory Committee. Updates include:

- In November 2015, MCR completed its yearly data submission to both the Centers for Disease Control and Prevention's National Program of Cancer Registries and the North American Association of Cancer Registries. The MCR is currently finalizing the 2013 data for release.
- The MCR is currently working with the DHMH Meaningful Use Group to register eligible providers.
- The MCR is finalizing plans to outreach to Maryland oncologist and hematologist membership associations to communicate Maryland Cancer Registry reporting requirements.
- The MCR continues to produce issues of their E-update to share information with MCR reporters.

### **Legislative Session Discussion**

Dr. Watkins updated the Council that the Legislative Subcommittee volunteers include Kala Visvanathan, Stephanie Cooper Greenberg, and Kevin Cullen.

The Council discussed the FDA proposed rule that would restrict sunlamp product use to adults age 18 and older (see handouts). The FDA is accepting public comments through March 21, 2016. The Council agreed that it should submit a comment in support of the FDA proposed rule, as it has supported statewide legislative efforts to prohibit minors' access to indoor tanning in the past.

### **Future Meetings**

The next Council meeting will be held on May 13, 2016 at Anne Arundel Medical Center from 9:30-11:30 a.m. Future 2016 Council meeting dates were provided to the Council (see handout).



**Maryland State Council on Cancer Control**  
**September 25, 2015**

**Meeting Summary**

**Members in Attendance**

Kathleen Connors-Juras  
Stephanie Cooper-Greenberg  
Diane Couchman  
Catherine Fenwick  
Mary Garza  
Donna Gugel  
Roger Harrell  
Christine Marino  
Jed Miller  
Joan Mischtschuk (formally Daughtery)  
William Nelson  
Delegate Sheree Sample-Hughes  
Artie Shelton  
Yale Stenzler  
Kala Visvanathan  
Stanley Watkins

**Members Absent**

Kevin Cullen  
Kim Herman  
Kevin Kelly  
Senator Anthony Muse  
Jay Perman  
Paul Rothman  
Brock Yetso

**Staff and Guests in Attendance**

Dawn Berkowitz  
Sarah Conolly Hokenmaier  
Nanyamka Hales  
Courtney Lewis  
William Tillburg  
Meredith Truss  
Olesya VERNYI-Kellogg

**Welcome and Review of Minutes**

The Council approved minutes from the May 15, 2015 meeting.

## **Membership Updates**

Lisa Gallicchio resigned from the Council as member and Cancer Registry Advisory Committee (CRAC) Chair as of July 2015 due to a new role with the National Cancer Institute (NCI). Lisa has been approved by NCI to continue with the Council as an NCI Advisor. Kala Visvanathan, Council Member and Associate Professor in Oncology and Epidemiology at Johns Hopkins Schools of Public Health and Medicine, has accepted the appointment of the CRAC Chair role.

Mary DeShields has chosen not to seek reappointment on the Council as of June 30, 2015. Wendy Friar has resigned from the Council on September 15, 2015.

There are currently two Council member openings. The Governor is responsible for appointing members to the Council, however if members have suggestions for his consideration they may be submitted to Nanyamka Hales or Dr. Watkins.

## **Electronic Nicotine Delivery Systems (ENDS) in Maryland**

(William Tillburg, JD, Deputy Director, Legal Resource Center for Public Health Policy, University of Maryland Carey School of Law)

William Tillburg presented a comprehensive overview of electronic cigarettes (see attached).

## **Legislative Session Discussion**

The Council discussed the need for three or four members to volunteer for a legislative subcommittee to draft Council positions this fall for bills that the Council may be interested in supporting during the 2016 legislative session (January – April 2016). This would ensure that the Council is prepared when bills are introduced, as there is generally a very short turn-around period for positions to be submitted. There were no volunteers during the meeting. If a member is interested in volunteering to draft Council positions in advance of the session, please contact Nanyamka Hales.

The Council focused its legislative discussion on changing its approach to supporting a ban on tanning bed access for minors. Kathleen Connors-Juras was asked to research PSAs from the American Cancer Society. Update: The American Cancer Society and ACSCAN do not have television or radio PSA's, but written materials are available. The National Council on Skin Cancer Prevention does have relevant PSA videos (<http://www.truthaboutindoortanning.org/action/videos>) and the Skin Cancer Foundation has some related materials as well (<http://www.skincancer.org/media-and-press/psa-and-testimonials>).

The Council discussed drafting a position in advance to support adding ENDS to the Clean Indoor Air Act (2015 House Bill 26, which will probably be reintroduced in 2016).

## **Maryland Cancer Plan Update**

Meredith Truss updated the Council on the status of the Maryland Comprehensive Cancer Control Plan, which has been updated for 2016-2020. DHMH has led the update process, which included two meetings to collect feedback from external partners in May and June 2015. Several Council members participated in these meetings and provided feedback. The Cancer Plan draft is being reviewed by DHMH leadership, and should be released in early 2016.

## **Maryland Cancer Collaborative Update**

Joan Daugherty updated the Council on activities of the Maryland Cancer Collaborative (see attached). The MCC has been heavily involved with the Cancer Plan update in 2015.

## **Maryland Cancer Registry Advisory Committee (CRAC) Update**

Kala Visvanathan updated the Council on activities of the CRAC. Updates include:

- The National Program of Cancer Registries has recognized the Maryland Cancer Registry (MCR) as a Registry of Distinction.
- The MCR continues to work with the DHMH Meaningful Use Group to register eligible providers and to resolve issues that prevent providers from submitting appropriate test files.
- The MCR continues to produce issues of their E-update to share information with MCR reporters.

## **2015 Cancer Conference**

The 2015 Cancer Conference will be held at Anne Arundel Medical Center on November 17, 2015 (see attached draft agenda). Registration will be capped at 300 this year due to space constraints. Sponsors include Anne Arundel Medical Center, University of Maryland Greenebaum Cancer Center, Johns Hopkins Kimmel Cancer Center, the American Cancer Society, the Johns Hopkins Greenberg Bladder Cancer Institute, and the Ulman Cancer Fund. Most speakers on the agenda have been confirmed except for the Emerging Best Practices Panel presenters, who will be chosen in early October based on submissions. There were seven abstracts submitted for review, and seven Abeloff nominations. Thank yous were provided to all of this year's sponsors and members of the Cancer Council that volunteered for the Abeloff Award and Emerging Best Practices review committees.

## **Cancer Council Letters of Support for Grant Applications**

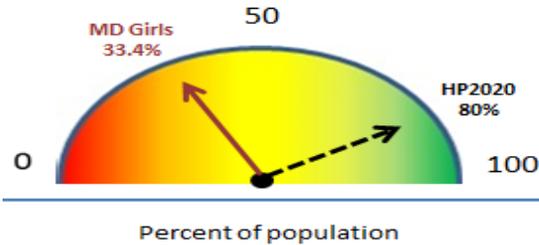
The Council discussed the possibility of providing letters of support to other entities for grant applications. It was decided that the Council would not become involved with supporting grant applications.

## **Future Meetings**

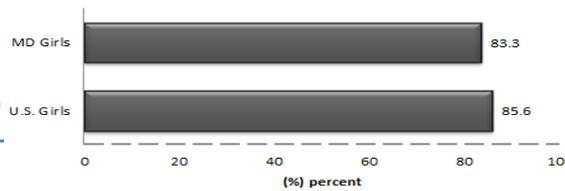
The Council will continue to meet at Anne Arundel Medical Center. The Council will meet in Classroom 5 for 2016 meetings. A schedule of 2016 meeting dates was distributed (see attached), which included a hold date for the 2016 Cancer Conference. The next meeting will be held on January 22, 2016 at Anne Arundel Medical Center, Classroom 5 from 9:30-11:30 a.m.

# Maryland: Human Papillomavirus Cancer & Prevention Profile

## HPV Vaccination Rates & Missed Opportunities (13-17 yrs; NIS-Teen 2013)

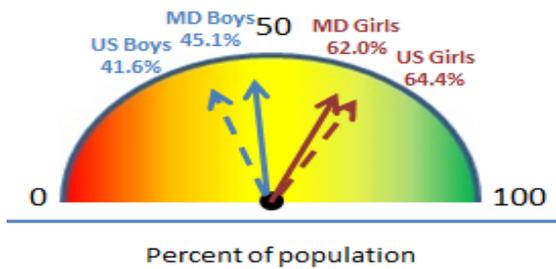


Percent of Unvaccinated Girls with Missed Opportunities

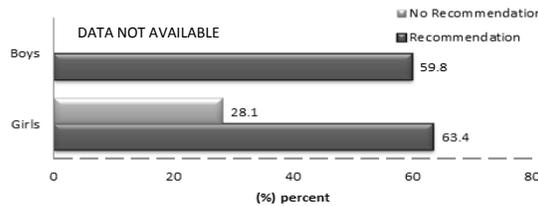


Healthy People 2020: Goal is 80% HPV vaccine (3 shots) coverage for boys and girls by age 13-15 years

## Prevalence of Provider Recommendations (13-17 yrs; NIS-Teen 2013)

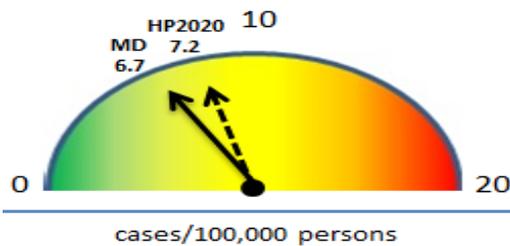


Vaccine Coverage by Receipt of Provider Recommendation

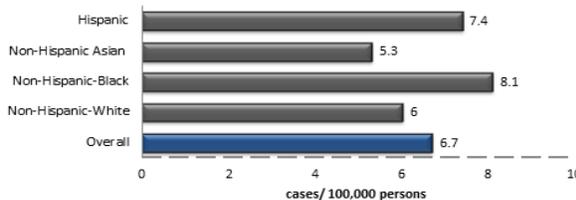


A strong provider recommendation is the most effective method for encouraging HPV vaccination

## Cervical Cancer – New Cases per Year (USCS 2007-2011)

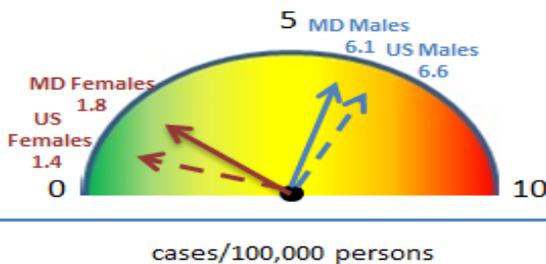


Cervical Cancer Incidence Rate by Race/Ethnicity

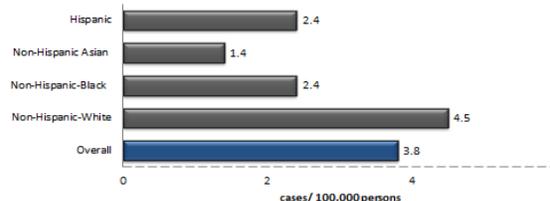


81% of new cases of cervical cancer could be prevented by HPV vaccination

## Oropharyngeal Cancer – New Cases per Year (USCS 2007-2011)



Oropharyngeal Cancer Incidence Rate by Race/Ethnicity



Racial/Ethnic minorities and low-income individuals suffer poorer HPV cancer outcomes

Contact your Area Health Education Center HPV Ambassador for information on professional education opportunities about HPV Vaccination.

Jennifer Berkman, Continuing Education Coordinator  
Eastern Shore Area Health Education Center  
(410) 221-2600

[jberkman@esahec.org](mailto:jberkman@esahec.org)

This work was supported by Cooperative Agreement #1H23IP000960 from the Centers for Disease Control and Prevention.



Human Papillomavirus Vaccination is Cancer Prevention.

# HOW TO READ THIS DOCUMENT



## HPV Vaccination Rates & Missed Opportunities

- Human papillomavirus (HPV) vaccination rates presented on the dashboard are state data for adolescents aged 13-17 years who have received all three doses in the HPV series according to the National Immunization Survey-Teen (NIS-Teen) from 2013.
- The bar chart data indicate the percent of unvaccinated state and national girls who had a missed opportunity. According to the CDC, a missed opportunity includes a health care encounter on or after 11th birthday, and on or after the publication of the ACIP recommendation for HPV vaccine (March 23, 2007 for girls; December 23, 2011 for boys) during which  $\geq 1$  vaccine was administered but not the 1st dose of the HPV vaccine series.
- Healthy People 2020 includes objectives for both male and females which read: “Increase the vaccination coverage level of 3 doses of human papillomavirus (HPV) vaccine for [females/males] by age 13 to 15 years.” For US girls, the 2008 baseline was 16.6% and for US boys the 2012 baseline was 6.9%. The target for both boys and girls is 80% and data are from the NIS-Teen.

## Prevalence of Provider Recommendations

- Data on the dashboard represent the percent of state (solid line) and US (dashed line) boys (in blue) and girls (in red) who received a provider recommendation. According to the CDC, a provider recommendation is when a parent/guardian reported receiving recommendation for HPV vaccine from their teen’s clinician according to the NIS-Teen from 2013.
- The bar chart shows vaccine coverage by receipt of provider recommendation for boys and girls 13-17 years old, when data was available from the NIS-Teen, 2013. For those who did not have a provider recommendation, light gray bars show the percent of boys and girls who received  $\geq 1$  dose of the HPV vaccine. For those who did receive a provider recommendation, dark gray bars show the percent of boys and girls who received  $\geq 1$  dose of the HPV vaccine. In most states, the bar graph shows that provider recommendation results in a greater percent of boys and girls vaccinated than when a provider does not recommend the vaccine.
- A strong provider recommendation is the most effective method for encouraging HPV vaccination – See references 4-6 below.

## Cervical Cancer – New Cases per Year

- Data on the dashboard represents the state cervical cancer incidence rate (solid line), or number of new cases per year per 100,000 persons according to the 2007-2011 data in the US Cancer Statistics (USCS) database. For comparison, the Healthy People 2020 goal of 7.2 cases/100,000 females is also shown (dashed line). The baseline for the U.S. from 2007 was 8.0/100,000 (USCS).
- The bar chart comes from the same source but breaks the cervical cancer incidence down by race and ethnicity. Subgroups shown vary by state based on the data available. Hispanic ethnicity includes all races.
- 81% of new cases of cervical cancer could be prevented by HPV vaccination. This statement is based on very recent research on the new 9-valent HPV vaccine (Gardasil©9) – See Saraiva et al. reference below for more information.

## Oropharyngeal Cancer – New Cases per Year

- Data on the dashboard represents the state (solid line) and national (dashed line) oropharyngeal cancer incidence rates, or number of new cases per year per 100,000 persons according to the 2007-2011 data in the USCS database. When available, data for both men (blue) and women (red) are shown.
- The bar chart comes from the same source but breaks the oropharyngeal cancer incidence down by race and ethnicity. Subgroups shown vary by state based on the data available. All bars include male and female data. Hispanic ethnicity includes all races.
- Racial/ethnic minorities and low-income individuals suffer poorer HPV cancer outcomes. There are a number of factors that impact this statistic, but the data are clear that racial/ethnic minority women and women living below the poverty line are more likely to become infected with HPV and get cervical cancer compared to Whites and higher income individuals. – See Hariri et al. reference and USCS below for more information.

## References

1. National Immunization Survey-Teen [http://www.cdc.gov/nchs/nis/data\\_files\\_teen.htm](http://www.cdc.gov/nchs/nis/data_files_teen.htm)
2. United States Cancer Statistics <http://wonder.cdc.gov/cancer-v2011.html>
3. Healthy People 2020. <http://www.healthypeople.gov>
4. Lau M, Lin H, Flores G. Factors associated with human papillomavirus vaccine-series initiation and healthcare provider recommendation in US adolescent females: 2007 National Survey of Children's Health. *Vaccine*. 2012 Apr 26;30(20):3112-8.
5. Vadaparampil S, Malo T, Kahn J, et al. Physicians' Human Papillomavirus Vaccine Recommendations, 2009 and 2011. *American Journal of Preventive Medicine*. 2014;46(1):90-84.
6. Saraiva M, Unger E, Thompson T, Lynch C et al. US Assessment of HPV Types in Cancers: Implications for Current and 9-Valent HPV Vaccines. *Journal of National Cancer Institute*. 2015; 107(6):1-12.
7. Hariri S, Unger E, Sternberg M, Dunne E, Swan D, Patel S, et al. Prevalence of genital human papillomavirus among females in the United States, the National Health And Nutrition Examination Survey, 2003-2006. *J Infect Dis* 2011; 204:566-73

*Human Papillomavirus Vaccination is Cancer Prevention.*

# NCI-designated Cancer Centers Urge HPV Vaccination for the Prevention of Cancer

Approximately 79 million people in the United States are currently infected with a human papillomavirus (HPV) according to the Centers for Disease Control and Prevention (CDC), and 14 million new infections occur each year. Several types of high-risk HPV are responsible for the vast majority of cervical, anal, oropharyngeal (middle throat) and other genital cancers. The CDC also reports that each year in the U.S., 27,000 men and women are diagnosed with an HPV-related cancer, which amounts to a new case every 20 minutes. Even though many of these HPV-related cancers are preventable with a safe and effective vaccine, HPV vaccination rates across the U.S. remain low.

Together we, the National Cancer Institute (NCI)-designated Cancer Centers, recognize these low rates of HPV vaccination as a serious public health threat. HPV vaccination represents a rare opportunity to prevent many cases of cancer that is tragically underused. As national leaders in cancer research and clinical care, we are compelled to jointly issue this call to action.

According to a 2015 CDC report, only 40 percent of girls and 21 percent of boys in the U.S. are receiving the recommended three doses of the HPV vaccine. This falls far short of the goal of 80 percent by the end of this decade, set forth by the U.S. Department of Health and Human Service's Healthy People 2020 mission. Furthermore, U.S. rates are significantly lower than those of countries such as Australia (75 percent), the United Kingdom (84-92 percent) and Rwanda (93 percent), which have shown that high vaccination rates are currently achievable.

The HPV vaccines, like all vaccines used in the U.S., passed extensive safety testing before and after being approved by the U.S. Food and Drug Administration (FDA). The vaccines have a safety profile similar to that of other vaccines approved for adolescents in the U.S. Internationally, the safety of HPV vaccines has been tested and approved by the World Health Organization's Global Advisory Committee on Vaccine Safety.

CDC recommends that boys and girls receive three doses of HPV vaccine at ages 11 or 12 years. The HPV vaccine series can be started in preteens as early as age 9 and should be completed before the 13th birthday. The HPV vaccine is more effective the earlier it is given; however, it is also recommended for young women until age 26 and young men until age 21.

The low vaccination rates are alarming given our current ability to safely and effectively save lives by preventing HPV infection and its associated cancers. Therefore, the 69 NCI-designated Cancer Centers urge parents and health care providers to protect the health of our children through a number of actions:

- We encourage all parents and guardians to have their sons and daughters complete the 3-dose HPV vaccine series before the 13th birthday, and complete the series as soon as possible in children aged 13 to 17. Parents and guardians should talk to their health care provider to learn more about HPV vaccines and their benefits.
- We encourage young men (up to age 21) and young women (up to age 26), who were not vaccinated as preteens or teens, to complete the 3-dose HPV vaccine series to protect themselves against HPV.
- We encourage all health care providers to be advocates for cancer prevention by making strong recommendations for childhood HPV vaccination. We ask providers to join forces to educate parents/guardians and colleagues about the importance and benefits of HPV vaccination.

HPV vaccination is our best defense in stopping HPV infection in our youth and preventing HPV-related cancers in our communities. The HPV vaccine is CANCER PREVENTION. More information is available from the [CDC](http://www.cdc.gov).



## Maryland Cancer Collaborative Update – February 2016

The goal of the Maryland Cancer Collaborative (MCC) is to work with individuals and organizations throughout the state to implement the Maryland Comprehensive Cancer Control Plan.

### UPDATE:

- A reminder that the Collaborative is on Facebook! Don't forget to follow us- you don't have to have a Facebook account to view the page. However if you are on Facebook and "like" the MCC, you can post updates and share information with other followers. The page can be found at:  
[www.facebook.com/marylandcancercollaborative](http://www.facebook.com/marylandcancercollaborative)
- The 2015 Cancer Plan Progress Report: Cancer Control Success Stories was released earlier this month. The report features updated data on goals and objectives in the Maryland Comprehensive Cancer Control Plan and several implementation success stories, many featuring Maryland Cancer Collaborative member organizations. The reports is available online at: <http://phpa.dhmh.maryland.gov/cancer/cancerplan/Pages/publications.aspx>
- The 2016-2020 Maryland Comprehensive Cancer Control Plan content has been approved by DHMH, and is currently being formatted by a graphic designer. The Cancer Plan should be released in or around April 2016.
- The Maryland Cancer Collaborative will hold its annual meeting in late spring 2016 (April or May). During this meeting the MCC will review strategies from the updated Cancer Plan and choose priorities to implement over the coming years. It will be an important meeting that will shape the future of the MCC and presents a great opportunity for anyone who is interested to join and get involved.
- Collaborative Committees continue to implement their Action Plans:
  - *Tobacco Workgroup*: The Tobacco Workgroup surveyed college campuses in the state about tobacco policies and available cessation services. The workgroup has analyzed its survey results and created a summary report that it will share with colleges this spring, along with best practices and resources for creating tobacco-free campuses. The workgroup is also looking into success stories of Maryland colleges that have gone tobacco-free to disseminate.
  - *Palliative Care Workgroup*: The Palliative Care Workgroup is working to raise awareness about palliative care among primary care providers by sharing resources with professional associations in the state to disseminate to members. The resources are intended to educate primary care providers as well as patients about palliative care. The resource list is available online at: [goo.gl/NDvXXE](http://goo.gl/NDvXXE).
  - *Evaluation*: The Evaluation Committee continues to work with other committees on evaluation as needed. The committee assisted the palliative care workgroup in the development of its hospital survey, and assisted the tobacco workgroup with its survey development.

### Next Steps

Continue **implementation!** Organizations implementing a goal, objective, or strategy from the Maryland Comprehensive Cancer Control Plan should submit an **Implementation Reporting Tool** to be considered for publication in statewide and/or national Success Stories publications, like the Annual Cancer Plan Progress Report. The Implementation Reporting Tool can be found at:

<http://phpa.dhmh.maryland.gov/cancer/cancerplan/SiteAssets/SitePages/Home/Implementation%20Reporting%20Tool.pdf>.

## The 22<sup>nd</sup> Annual Maryland State Council on Cancer Control Cancer Conference November 17, 2015

The 22<sup>nd</sup> Annual Maryland State Council on Cancer Control Cancer Conference was held on November 17, 2015 at the Anne Arundel Medical Center Doordan Conference Center. Three hundred thirty-one (331) individuals from across Maryland registered for the conference and 285 individuals attended the conference. The conference evaluation survey was sent on November 19, 2015 to the 269 attendees who provided an e-mail address when they registered for the conference. The survey was closed on December 4, 2015.

**Table 1: Summary of Attendees**

Total # of Individuals Registered	331
Total # of Attendees	285
Total # of Attendees who Received Evaluation Request	269
Total # of Evaluation Responses	121
Evaluation Response Rate	45%*

\*Response rate is calculated based on the # of evaluation responses compared to the # of attendees who received the evaluation request.

**Table 2: Overall Evaluation of the Conference**

	Excellent	Good	Neutral	Fair	Poor	Total (n)
<b>Quality of Conference</b>	<b>63%</b> (n=76)	<b>31%</b> (n=37)	<b>4%</b> (n=5)	<b>2%</b> (n=2)	<b>0%</b> (n=0)	120
<b>Accessibility</b>	<b>57%</b> (n=57)	<b>37%</b> (n=44)	<b>4%</b> (n=5)	<b>2%</b> (n=2)	<b>0%</b> (n=0)	118
<b>Convenient Location</b>	<b>53%</b> (n=64)	<b>37%</b> (n=45)	<b>4%</b> (n=5)	<b>3%</b> (n=4)	<b>2%</b> (n=2)	120
<b>Time of Event</b>	<b>53%</b> (n=63)	<b>41%</b> (n=48)	<b>5%</b> (n=6)	<b>1%</b> (n=1)	<b>0%</b> (n=0)	118
<b>Audio/Visual Set-Up</b>	<b>62%</b> (n=73)	<b>35%</b> (n=41)	<b>2%</b> (n=2)	<b>2%</b> (n=2)	<b>0%</b> (n=0)	118

### Learning Objectives

At least 90% of those who responded to the evaluation survey agreed or strongly agreed that following the conference they:

- Understood the content and status of the 2016-2020 Maryland Comprehensive Cancer Control Plan;
- Understood the relationship between HPV and cancer, and could identify methods to increase HPV vaccination in the community;
- Understood how cancer impacts employees and could identify best practices in the development of workplace programs for working cancer patients and survivors; and
- Understood the financial impact of cancer on patients and families.

At least 87% of those who responded to the evaluation survey agreed or strongly agreed that following the conference they:

- Understood how diet influences high burden cancers in Maryland; and
- Were able to identify emerging best practices in cancer control related to building a hospital-based palliative care program.

At least 73% of those who responded to the evaluation survey agreed or strongly agreed that following the conference they:

- Were able to identify emerging best practices in cancer control related to improving breast cancer screening and diagnosis among Latina women, and in the use of low dose computed tomography for adults at high risk of lung cancer.

**The 22<sup>nd</sup> Annual Maryland State Council on Cancer Control Cancer Conference  
November 17, 2015**

**Overall there were many positive comments regarding the conference**, such as the conference was “excellent”, “great”, “wonderful”, “informative”, and “well presented”. The speakers were “knowledgeable”; some were “excellent” and “engaging”. However, there were some **suggestions for improvement**, such as:

- Having handouts available before or at the conference;
- “More engaging presentations”, and “Passionate speakers who will engage the audience”; “Many speakers seemed to use presentations fit for clinical engagements vs. public health”;
- Having less speakers;
- “Have best practices presentations talk more about how to implement rather than just describe their programs and successes”; and
- “More about community, local, and state programs showing how data and research can be applied”.

**Table 3: Suggestions for Future Conferences**

<b>Program or Policy Updates</b>	<ul style="list-style-type: none"> <li>• Include a community hospital or provider in the presentations;</li> <li>• More about insurance companies and their take on screening process for cancers;</li> <li>• Wellness in work environment;</li> <li>• Survivorship care plans in Maryland hospitals;</li> <li>• Continue having presentations on the prevention of cancer including research and innovative community projects;</li> <li>• Impact of ACA implementation on cancer prevention and care;</li> <li>• Electronic cigarettes;</li> <li>• Presentation on building consensus on cancer screening recommendations;</li> <li>• Role of community leaders for promoting cancer prevention;</li> <li>• Topics on tobacco and cancer; and more information on implementation goals in the community;</li> <li>• Integrative health options in cancer care patient navigation; and</li> <li>• Provide extra time about HPV and the Hispanic, Korean, Pacific Islander, etc., populations.</li> </ul>
<b>Research and Treatment</b>	<ul style="list-style-type: none"> <li>• Prevention of cancer;</li> <li>• Nutrition and lifestyle: physical activity and specific nutrients;</li> <li>• Cancer pain;</li> <li>• Palliative care and how to discuss it with doctors; the cost saving measure of palliative care;</li> <li>• Childhood cancer;</li> <li>• Breakout session on cancers that do not get a lot of attention (uterine, ovarian, bladder, etc.);</li> <li>• Presentation on mutational analysis of tumors and how targeted therapy and immunotherapy are being used; and</li> <li>• The cost of drugs and why they are so high.</li> </ul>
<b>Resources</b>	<ul style="list-style-type: none"> <li>• Provide new resources/tools/novel ideas for implementing the Cancer Plan.</li> </ul>

## **Proposed Cancer Conference/MCC Meeting Agenda**

- 8:40-8:50 Welcome
- 8:50-9:10 Opening Remarks
- 9:10-10:10 Keynote (1 hour incl. Q&A)
- 10:10-11:00 Speaker (50 minutes incl. Q&A)
- 11:00-11:15 Break
- 11:15-12:15 Panel: Data/Burden Update (15 mins), Cancer Center Research Updates (30 mins), Q&A
- 12:15-12:30 Council Awards
- 12:30-1:30 Closing Remarks and Lunch
- 1:30-1:45 Set-up for MCC Meeting
- 1:45-4:00 MCC Meeting & Workgroup Meetings  
(split up into small groups within ballroom like Cancer Plan meeting at UMBC for workgroup meetings)

# FDA Proposes New Safety Measures for Indoor Tanning Devices: The Facts



[En Español \(/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspañol/ucm477929.htm\)](#)

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On this page:

- [How This Announcement Could Affect You](#)
- [You Can Comment on Proposed Rules](#)
- [What to Know If You Still Plan to Use an Indoor Tanning Device](#)

There are many risks from indoor tanning devices: Using sunlamp products such as indoor tanning beds or booths exposes you to [ultraviolet \(UV\) radiation \(/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/Tanning/ucm116425.htm\)](#) and increases your risk of eye injury, skin damage, and skin cancer—including melanoma, the deadliest type of skin cancer.

Due to these risks, the FDA already requires indoor tanning devices to be labeled with a visible, black-box warning stating that they should not be used by people under age 18. We know that the effects of exposure to UV radiation add up over one's lifetime. Therefore, UV radiation exposure in youth and teenagers puts them at a greater risk for skin and eye damage later in life. That's why the FDA now is proposing a rule to protect youth from the risks of these devices by restricting use only to adults age 18 and older. This proposed rule also would require indoor tanning facilities to inform adult users about the health risks of indoor tanning and to obtain a signed risk acknowledgement from these users.

The agency also is proposing a second rule that would require manufacturers and indoor tanning facilities to take more actions to help improve the overall safety of indoor tanning devices to protect adult consumers.

“There is increasing evidence that indoor tanning during childhood and early adult life increases the risk of skin cancer, including melanoma,” says Markham C. Luke, M.D., Ph.D., a dermatologist and the deputy office director of the Office of Device Evaluation at the FDA's Center for Devices and Radiological Health. “Hundreds of youth also are injured each year across the country due to using sunlamp products.”

In fact, people who have been exposed to radiation from indoor tanning are 59 percent more likely to develop melanoma than those who have never tanned indoors, according to the American Academy of Dermatology.

On average, more than 3,000 emergency room visits in the United States happen each year because of injuries related to indoor tanning (based on data from 2003 through 2012), according to the Centers for Disease Control and Prevention (CDC). More than 400 of those patients each year were individuals under age 18.

“The FDA is particularly concerned about children and teens being exposed to UV radiation from indoor tanning because the effects of exposure add up over your lifetime,” Luke explains. “Exposure to UV radiation from indoor tanning is a preventable cause of skin cancer. The FDA is committed to protecting public health by informing consumers of the risks of indoor tanning.”

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## **How This Announcement Could Affect You**

This action is intended to help protect youth from a known and preventable cause of skin cancer and other harms—and to help adults make decisions regarding tanning based on truthful information. The FDA is also acting to make sure manufacturers and tanning facilities take steps to help improve the safety of indoor tanning devices.

If the FDA's first proposed rule becomes final, indoor tanning facilities would not be allowed to use indoor tanning devices on people under age 18. This proposal is intended to help protect the health of American youth.

And, adult users would have to sign a certification acknowledging that they have been informed of the health risks related to the use of indoor tanning devices. Adults would sign this certification before their first indoor tanning session, and every six months after that.

This certification would help the FDA make sure indoor tanning facilities are giving truthful and easy-to-read information to consumers. This certification also would help adults make informed decisions.

If the FDA's second proposed rule on sunlamp products (regarding performance standards) becomes final, it would require manufacturers and indoor tanning facilities to take more actions to protect consumers. (Performance standards, among other things, help ensure devices function as intended, which can help reduce risks to consumers.)

Some key proposed changes would include:

- Changing requirements for warning statements to make them more effective;
- Improving eye safety by adding requirements that would limit the amount of visible light allowed through protective eyewear to protect consumers' eyes from intense light;
- Improving labeling on replacement bulbs so tanning facility operators make sure they are using the correct bulbs, reducing the risk of accidental burns;
- Preventing changes to devices (for instance, preventing manufacturers from installing stronger bulbs) without re-certifying and re-identifying the device with the FDA; and
- Requiring all sunlamp products to have an emergency shut-off switch (or panic button) that users can easily find and identify by touch or sight.

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## **You Can Comment on Proposed Rules**

The two proposed rules are available online for public comment for 90 days. (See [blue box](#) below for links and instructions.)

"We want to hear from all users and their families, as well as from manufacturers, business owners, and other stakeholders who might have comments," says Luke. "We will review all comments and viewpoints as part of the rule-making process."

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## **What to Know If You Still Plan to Use an Indoor Tanning Device**

The FDA is proposing measures to reduce the risks posed by these devices. Users should remember that sunlamp products currently must include statements on the device warning against their use by youth under 18.

Also understand the following points.

- Failure to wear appropriate protective eyewear, such as goggles, can lead to short- and long-term eye injury.
- Long exposures (close to the maximum time for the sunlamp product), can lead to burning. Because sunburn takes 6 to 48 hours to develop, you may not realize your skin is burned until it is too late.
- You should follow the manufacturer's recommended exposure times on the label. People with skin that burns easily and does not tan should never use indoor tanning devices.
- Tanning while using certain medications or cosmetics may make you more sensitive to UV radiation. Talk to your doctor or pharmacist first.

## How to Comment on the Proposed Rules

To comment on the Restricted Sale, Distribution, and Use of Sunlamp Products:

1. Read the [proposed rule \(http://www.regulations.gov#!documentDetail;D=FDA-2015-N-1765-0001\)](http://www.regulations.gov#!documentDetail;D=FDA-2015-N-1765-0001).
2. Starting Tuesday, December 22, submit comments on the proposed rule on Regulations.gov.

[Comment Now \(http://www.regulations.gov#!submitComment;D=FDA-2015-N-1765-0001\)](http://www.regulations.gov#!submitComment;D=FDA-2015-N-1765-0001)

To comment on the Amendment to the Performance Standard for Sunlamp Products:

1. Read the [proposed rule \(http://www.regulations.gov#!documentDetail;D=FDA-1998-N-0880-0004\)](http://www.regulations.gov#!documentDetail;D=FDA-1998-N-0880-0004).
2. Starting Tuesday, December 22, submit comments on the proposed rule on Regulations.gov.

[Comment Now \(http://www.regulations.gov#!submitComment;D=FDA-1998-N-0880-0004\)](http://www.regulations.gov#!submitComment;D=FDA-1998-N-0880-0004)

The comment period closes March 21, 2016.

This article appears on [FDA's Consumer Updates page \(/ForConsumers/ConsumerUpdates/default.htm\)](http://www.fda.gov/oc/forconsumers/consumerupdates/default.htm), which features the latest on all FDA-regulated products.

*December 22, 2015*

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### For More Information

- [Tanning \(/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/Tanning/default.htm\)](http://www.fda.gov/oc/radiation-emitting-products/radiation-emitting-products-and-procedures/tanning/default.htm)

## Related Consumer Updates

- [Indoor Tanning: The Risks of Ultraviolet Rays \(/ForConsumers/ConsumerUpdates/ucm186687.htm\)](/ForConsumers/ConsumerUpdates/ucm186687.htm)
- [Five Tips for a Safer Spring Break \(/ForConsumers/ConsumerUpdates/ucm389469.htm\)](/ForConsumers/ConsumerUpdates/ucm389469.htm)

## More in Consumer Updates (/ForConsumers/ConsumerUpdates/default.htm)

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[Children's Health \(/ForConsumers/ConsumerUpdates/ucm047364.htm\)](/ForConsumers/ConsumerUpdates/ucm047364.htm)

[Cosmetics \(/ForConsumers/ConsumerUpdates/ucm149191.htm\)](/ForConsumers/ConsumerUpdates/ucm149191.htm)

[Dietary Supplements \(/ForConsumers/ConsumerUpdates/ucm153239.htm\)](/ForConsumers/ConsumerUpdates/ucm153239.htm)

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[Nutrition \(/ForConsumers/ConsumerUpdates/ucm244206.htm\)](/ForConsumers/ConsumerUpdates/ucm244206.htm)

[Radiation-Emitting Products \(/ForConsumers/ConsumerUpdates/ucm149210.htm\)](/ForConsumers/ConsumerUpdates/ucm149210.htm)

[Tobacco Products \(/ForConsumers/ConsumerUpdates/ucm237634.htm\)](/ForConsumers/ConsumerUpdates/ucm237634.htm)

[Vaccines, Blood & Biologics \(/ForConsumers/ConsumerUpdates/ucm149184.htm\)](/ForConsumers/ConsumerUpdates/ucm149184.htm)

[Articulos en Espanol \(/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspanol/default.htm\)](/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspanol/default.htm)





## General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products

This Proposed Rule document was issued by the **Food and Drug Administration (FDA)**

For related information, [Open Docket Folder](#)

[Comment Now!](#)

Due Mar 21 2016, at 11:59 PM ET

### Action

Proposed rule.

### Summary

The Food and Drug Administration (FDA or the Agency) is proposing to establish device restrictions for sunlamp products, which would restrict their use to individuals age 18 and older, require prospective users to sign a risk acknowledgement certification before use, and require the provision of user manuals.

### Dates

Submit either electronic or written comments on the proposed rule by March 21, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 22, 2016. See Section VIII for the proposed effective date of a final rule based on this proposed rule.

### Addresses

FDA is explicitly seeking comment on the risks to health that should be included in the risk acknowledgement certification. You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

**Instructions:** All submissions received must include the Docket No. FDA-2015-N-1765 for "General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products." Received comments will be placed in the docket and, except for those submitted as

ID: FDA-2015-N-1765-0001

View original printed format:

### Document Information

**Date Posted:**

Dec 22, 2015

**RIN:**

0910-AH14

**CFR:**

21 CFR Part 878

**Federal Register Number:**

2015-32024

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### Comments

80

Comments Received\*

*This legislation is necessary. Too many young people in their teens and twenties are getting melanoma now. Parents aren't aware of the dangers until their kid...*

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*To whom it may concern, I am completely taken back by the new proposal that the FDA is considering. This is another example of a government agency trying to...*

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*This is just another political scam masquerading as guardians of our well-being that ultimately serves the dermatologists association, pharmaceutical industry...*

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"Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the title "Restricted Sale, Distribution, and Use of Sunlamp Products."

## For Further Information Contact

Neil R.P. Ogden, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1438, Silver Spring, MD 20993-0002, 301-796-6397.

## Supplementary Information

### I. Background and Legal Authority

Sunlamp products are both "devices" under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)), and "electronic products" under section 531(2) of the FD&C Act (21 U.S.C. 360hh(2)). They are designed to incorporate one or more ultraviolet (UV) lamps intended for irradiation of any part of the living human body, by UV radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning (see §§ 878.4635(a) and 1040.20(b)(9) (21 CFR 878.4635(a) and 1040.20(b)(9))). Sunlamp products include tanning beds and tanning booths. Sunlamp products, as defined in proposed § 878.4635, do not include—and this proposed rulemaking does not address—ultraviolet lamps for dermatological disorders regulated under 21 CFR 878.4630. <sup>(1)</sup>

The FD&C Act establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) defines three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

FDA regulates electronic products under chapter 5, subchapter C, of the FD&C Act (21 U.S.C. 360hh *et seq.*). Under these provisions, FDA administers an electronic product radiation control program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products.

FDA is undertaking three initiatives to address the risks associated with sunlamp products. First, in a final reclassification order that issued June 2, 2014 (79 FR 31205 at 31213), FDA reclassified sunlamp products and UV lamps intended for use in sunlamp products from class I to class II, and established special controls and premarket notification (510(k)) requirements under the medical device authorities of the FD&C Act. The special controls include performance

## Docket Information

This document is contained in  
[FDA-2015-N-1765](#)

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testing and labeling requirements, including a warning that sunlamp products are not to be used on persons under the age of 18 years.

Second, and simultaneously with this proposed rule, FDA is proposing amendments to the sunlamp products and UV lamps performance standard at § 1040.20, which includes technical and labeling requirements issued under the radiological health provisions of the FD&C Act. As explained elsewhere in this issue of the Federal Register, FDA is taking this action to reflect current scientific knowledge related to sunlamp product use, harmonize it more closely with International Electrotechnical Commission (IEC) International Standard 60335-2-27, Ed. 5.0: 2009-12, and strengthen the warning statement required by § 1040.20(d)(1)(i) in accordance with the results of the study FDA conducted under section 230 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85).

Finally, in this action, FDA is proposing device restrictions under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), which authorizes FDA to issue regulations imposing restrictions on the sale, distribution, or use of a device, if, because of its potentiality for harmful effects or the collateral measures necessary to its use, FDA determines that absent such restrictions, there cannot be a reasonable assurance of its safety and effectiveness. The proposed device restrictions would require that:

1. Tanning facility operators permit use of sunlamp products only if the prospective user is age 18 or older;
2. Tanning facility operators, upon request by the user or prospective user, provide a copy of the sunlamp product user manual or name and address of the manufacture or distributor from whom a user manual may be obtained;
3. 510(k) holders assure that a user manual accompanies each sunlamp product and, upon request, provide a copy of the user manual to any tanning facility operator, user or prospective user; and
4. Tanning facility operators obtain each prospective user's signature on a risk acknowledgement certification.

These device restrictions would primarily apply to tanning facility operators, and to a lesser extent, device manufacturers and distributors. FDA considers a tanning facility operator to be any person offering for sale the use of sunlamp products. FDA would not consider people who use their own tanning beds (home users) to be tanning facility operators.

Certain provisions of the FD&C Act relate specifically to FDA's authority over restricted devices. For example, sections 502(q) and (r) of the FD&C Act (21 U.S.C. 352(q) and (r)) provide that a restricted device distributed or offered for sale in any state shall be deemed to be misbranded if its advertising is false or misleading or fails to include certain information regarding the device, or it is sold, distributed, or used in violation of regulations prescribed under section 520(e), and section 704(a) of the FD&C Act (21 U.S.C. 374(a)) authorizes FDA to inspect certain records relating to restricted devices.

If this proposed rule becomes final, it may be enforced by means of seizure of the sunlamp product, under section 304 of the FD&C Act (21 U.S.C. 334); a suit for injunction, under section 302 of the FD&C Act (21 U.S.C. 332); imposition of civil money penalties, under section 303 of the FD&C Act (21 U.S.C. 333); or criminal prosecution, under section 303 of the FD&C Act. FDA expects to cooperate with counterpart agencies at the state level in enforcing the proposed requirements, if they become final. Consumer complaints to FDA and State Agencies would be important in identifying entities that violate the conditions for sale or use of these devices.

## II. Risks Posed by the Device

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (2010 Advisory Panel) met on March 25, 2010, to review and discuss recent information regarding the risks to the general public from exposure to sunlamp products, and identified the following risks to health for sunlamp products. <sup>(2)</sup> These risks are well documented and discussed in published literature.

### A. Increased Skin Cancer Risk From Cumulative, Repeated UV Radiation Exposure

UV radiation exposure can lead to permanent damage to DNA in the skin, which has been shown to lead to an increased risk of skin cancer (Refs. 1-3). Skin cancers that have been associated with cumulative repeated UV radiation exposure include melanoma and non-melanoma skin cancers (NMSC) such as basal cell carcinoma and squamous cell carcinoma (Ref. 4). One study suggests that doses of UV-A radiation emitted by high power sunlamp products may be up to 10 to 15 times higher than that of the midday sun, resulting in an intense amount of exposure that does not exist in nature (Ref. 5). Users with a personal history of

melanoma have an increased risk of skin cancer, as do users with familial melanoma—having one first-degree relative with melanoma doubles one's risk of developing melanoma (Refs. 6, 7). There is also evidence suggesting that individuals who begin indoor tanning at ages younger than 18 years are particularly vulnerable to the carcinogenic impact of indoor tanning (see section III.A for further discussion).

## B. Ocular Injury

UV and visible radiation from sunlamp products can be harmful to the eyes if proper protective eyewear is not worn. The UV radiation from sunlamp products can cause keratitis and corneal burns, which can be painful and affect vision (Ref. 8). The intense visible light from some sunlamp products can damage the retina and permanently affect vision (Ref. 8). Artificial UV radiation has also been linked to ocular melanoma, which can cause vision loss and often spreads to other parts of the body (Ref. 9).

## C. Discomfort, Pain, and Tenderness on the Skin Resulting From Burns to the Skin Due to Acute Overexposure to UV Radiation

A recent study showed that, despite protective properties touted by commercial tanning facilities such as claims that indoor tanning limits exposure time and intensity, 66 percent of female college-age users reported skin erythema (or redness due to sunburn) from indoor tanning, and these users reported one episode of sunburn out of every five tanning sessions (Ref. 10). Those findings are in line with a previous report that found that 58 percent of sunlamp product users ages 11 years to 18 years had experienced sunburns from exposure to sunlamp products (Ref. 11).

In certain individuals who are photosensitive, skin exposure to UV radiation may induce unexpected reactions such as rash, severe burns, and hypersensitivity (Ref. 12). Various drugs may cause a photosensitivity reaction in the skin. Some drugs may cause a phototoxic reaction when they absorb UV-A radiation and cause cellular damage. These drugs include anti-infective drugs such as tetracyclines and fluoroquinolones, cardiovascular drugs like hydrochlorothiazide and amiodarone, psychiatric drugs such as phenothiazines, and retinoids such as isotretinoin (Ref. 13). Some dietary supplements may also cause photosensitivity (Ref. 13).

Sunlamp products, like most light sources, generate heat that can cause thermal skin burns, similar to any hot surface. Individuals with open wounds or lesions are particularly susceptible to burns from UV radiation because these individuals lack the protective epidermal layer of the skin that provides the body's greatest protection from UV irradiation (Ref. 14).

## D. Skin Damage

Cumulative, repeated exposure to UV radiation emitted by sunlamp products may lead to accelerated aging of skin due in part to DNA and skin cell damage (Ref. 15). UV irradiation inhibits the production of collagen precursor molecules such as type I and type III procollagen (Ref. 16). UV irradiation stimulates skin metalloproteinases, which break down skin proteins that then lead to photoaging (Ref. 17). On a cellular level, UV radiation has been known to cause DNA damage (Ref. 1).

# III. Proposed Device Restrictions

FDA is proposing the following restrictions which, because of the potential for harmful effects from the device, are necessary for a reasonable assurance of safety and effectiveness of sunlamp products:

## A. Use Would Be Restricted to Individuals Age 18 and Older

Although the risks associated with sunlamp products are applicable to all persons, FDA is proposing to restrict the use of this device to persons age 18 and older because children and adolescents who are exposed to UV radiation may be at higher risk of developing certain types of skin cancer than persons who begin exposure later in life as adults (Ref. 18). In the final reclassification order for this device, FDA established special controls labeling regarding minors' use of sunlamp products and UV lamps intended for use in sunlamp products (see § 878.4635(b) (6)). Based on the increased risk of developing skin cancer and minors' difficulty in appreciating the risks posed by the devices (see Refs. 19 to 24), FDA has determined that use of sunlamp products by minors is not appropriate and is therefore establishing a proposed restriction in this rulemaking action to complement the special controls labeling.

Published medical evidence demonstrates that there is a direct correlation between sunlamp product use among youths and their developing melanoma skin cancer, as well as other skin cancers (Refs. 25, 26). Melanoma is a leading cause of cancer death in women ages 15 years to 29 years and there is some evidence that suggests use of sunlamp products is an underlying cause (Refs. 27, 28).

There is increasing epidemiological evidence that shows that tanning at ages younger than 18

years increases the risk of developing melanoma (Refs. 25, 29 to 32). Melanoma (of the types of skin cancer, this is the more concerning type due to greater potential for fatality) is currently the second leading type of cancer in persons age 20 years to 39 years, and many experts believe that at least one cause for this is the increasing use of sunlamp products (Refs. 30, 33). A 2009 International Agency for Research in Cancer (IARC) report linked UV exposure (including from indoor tanning devices) by individuals under age 35 to higher rates of melanoma as compared to a similar cohort of individuals who had not used sunlamp products, and recommended that minors not use sunlamp products. Similarly, a meta-analysis by Gallagher et al. that evaluated metrics of sunlamp product exposure, including in young adults, indicated a significantly increased risk of cutaneous melanoma subsequent to sunlamp product exposure (Ref. 34). In particular, the analysis showed a positive association between first exposure as a young adult and subsequent melanoma. Further, a case control study in Connecticut found a relative risk of 1.4 for melanoma diagnosis when individuals are exposed to sunlamp products before the age of 25 (Ref. 35).

In addition, there is increasing epidemiological evidence that shows that tanning at ages younger than 18 years increases the risk of developing NMSC. For example, recent studies found a significantly higher risk for basal cell carcinoma for individuals who used sunlamp products during high school and college as compared to those who used sunlamp products between the ages of 25 and 35 (Refs. 36, 37).

Individuals under 18 who are exposed to UV radiation are at an increased risk of developing skin cancer because (1) there is evidence suggesting that they are particularly vulnerable to the damaging effects of UV radiation and (2) the cumulative effects of exposure have been linked to higher incidence of skin cancer. First, evidence suggests that minors exposed to UV radiation are particularly vulnerable to developing skin cancer (Ref. 38). In particular, migration studies compare people who moved from less UV-intense environments to more UV-intense environments at a young age, for example, children who moved from the United Kingdom to Australia. A number of biological factors, such as skin development and formation of nevi at a young age, are identified as potentially causing the increase in the risk of developing melanoma from exposure to UV radiation, like that from sunlamps (Refs. 18, 39). Second, as with other radiation exposure, increased cumulative lifetime UV exposure results in increased skin cancer risk (Ref. 40).

The age restriction also is necessary because individuals under 18 often fail to appropriately evaluate the significant health risks associated with indoor tanning. For example, a study has shown that college age students often use sunlamp products despite awareness of the long-term risks (Refs. 41 to 43). Rather, persons under age 18 years appear to be discounting whatever risk information they are receiving or may have difficulty incorporating the information into their decisionmaking. For example, a recent study links indoor tanning by high school students to other risk-taking behaviors, including binge-drinking, unhealthy weight control, sexual intercourse, and illegal drug or steroid use (Ref. 20). This linkage suggests that, like other risk-taking behaviors, adolescents use sunlamp products for self-esteem or sensation seeking reasons, irrespective of known health risks (Ref. 20). Similarly, another recent study showed that psychosocial and demographic characteristics strongly correlated with adolescent indoor tanning (Ref. 22). By restricting sunlamp product use to individuals 18 and older, we would be protecting a subpopulation that generally tends to discount risk information and favor risk taking.

Based on the scientific evidence available at the time, some members of the 2010 Advisory Panel recommended an age restriction to preclude use by persons under 18 years of age to reduce the unintended health effects of these devices (Ref. 44). The scientific literature published since that meeting, as described in this document, offers further support for an age restriction (Refs. 20, 22, 41).

Various professional organizations also support an age restriction on sunlamp product use. The World Health Organization (WHO) has classified UV radiation from sunlamp products as a class I carcinogen based on the 2009 IARC report that linked sunlamp product use by individuals under age 35 to higher rates of melanoma and strongly urged consideration of restricting minors from using sunlamp products (Ref. 45). Accordingly, the WHO recommends that persons under age 18 not use sunlamp products (Ref. 46).

The American Academy of Dermatology (AAD) recognizes WHO's declaration that sunlamp products are cancer-causing agents and are in the same risk category as tobacco, and supports the position that minors should not use sunlamp products (Ref. 47). In 2011, the American Academy of Pediatrics published a policy statement similar to that of the AAD calling for a restriction on sunlamp product use by minors (Refs. 48, 49).

Experts in pediatrics, public health, and dermatology also support a legislative age restriction on sunlamp product use. For example, recent studies cited other peer reviewed articles to examine the effects of legislation on indoor tanning use (Refs. 22, 50, 51). They concluded that an age restriction or ban would be far more effective at reducing youth indoor tanning than other

potential actions such as parental consent (Refs. 22, 50, 51).

This scientific evidence also has led many State and foreign governments to institute age restrictions in the last few years on the use of sunlamp products by minors (Ref. 50). To date, more than 40 states have age restrictions on sunlamp product use (Ref. 52). These restrictions have age limits ranging from ages 14 to 18. At least 11 countries have restricted the use of sunlamp products to adults age 18 and older, including Great Britain and France (Refs. 52 to 54).

Restricting use of these devices to individuals 18 and over should reduce future morbidity and mortality from melanoma and other skin cancers and would help to protect the public health, according to both expert advisory opinion and findings from current scientific, medical, and public health policy literature (Ref. 54). In the journal *Health Policy* in 2009, Hirst et al. estimated that preventing minors from indoor tanning has the potential to reduce the incidence of skin cancers and related medical costs (Ref. 54).

This restriction is particularly important because, as previously discussed, it has been shown that increased knowledge of the risks of UV exposure among adolescents and young adults does not appreciably alter their tanning behavior and attitudes (Refs. 19, 41, 42, 55). The use of sunlamp products has been suggested to have both a psychological reinforcing effect in minors due to feedback from others on minors' cosmetic appearance or self-perceptions that leads to continued or increased use, in addition to the physical reinforcing effect that has been linked to high rates of use (Refs. 19, 56).

This age restriction is also important because parental awareness of the risks, educational campaigns, and parental consent to the risks, on their own, have been shown to be insufficient in reducing indoor tanning in young age groups (Refs. 21, 22, 41).

The risks associated with use of sunlamp products by individuals under 18 are particularly concerning given the widespread use of these devices among high school students. The Centers for Disease Control and Prevention has documented high rates of use in U.S. high school students from its 2011 Behavioral Risk Survey: 13 percent of all high school students report indoor tanning, and 29 percent of white female high school students report usage in the last year (Ref. 53). There are a number of collaborative studies that have demonstrated that young women, in particular, use sunlamp products at increasingly high rates (Refs. 22 to 24, 57). For example, one study found that indoor tanning usage (defined as tanning during the previous 12 months) progressively increased in adolescents (age 14-17) from 5.5 percent at age 14 to 16.5 percent at age 17, which suggests that adolescents use indoor tanning more often as they get older (Ref. 22). Another study analyzed the results of a survey of over 10,000 U.S. individuals age 12 years to 18 years and found nearly 10 percent of respondents used a sunlamp product during the previous year and rates increased to 35 percent for females by age 17, highlighting that teenage girls are more likely than their male counterparts to use indoor tanning facilities (Ref. 24).

FDA seeks comments on its proposal to restrict use of these devices to individuals 18 years of age and over as well as data and information in support of any comments. In addition, although FDA has strong reservations about a parent-consent process in this setting, we recognize parents' decision-making role. We welcome comment on parental consent and its potential scope, including comments on experiences in jurisdictions that have a parental consent provision for use of sunlamp products.

#### **B. Sunlamp Product User Manuals Would Have To Be Provided to Users, Prospective Users, and Tanning Facility Operators Upon Request**

User manuals provide valuable information to operators and users. Sunlamp product user manuals can include vital information such as instructions for use, exposure schedules, maintenance guidance, and device warnings. In order to help ensure the dissemination of this important information to sunlamp product users, FDA is proposing that tanning facility operators be required to provide a copy of the user manual or the name and address of the manufacturer or distributor that can provide a copy of the user manual to any user or prospective user that requests one. Similarly, FDA is also proposing that 510(k) holders be required to provide user manuals to any tanning facility operator, user, or prospective user that requests one. The electronic product performance standard currently requires manufacturers to provide manuals to purchasers and, upon request, to others for the life of the sunlamp product (see § 1040.20(e)). FDA believes that access to the information contained in the user manual would help prospective users make informed decisions when considering whether to use the device and would also inform tanning facility operators and users on how to use the device properly.

#### **C. Prospective Users Would Have To Sign a Risk Acknowledgement Certification Before Sunlamp Product Use**

FDA is proposing that tanning facility operators would have to provide, and sunlamp product

prospective users 18 and older would have to sign, the certification set forth in proposed § 878.4635(c)(4) prior to use of any sunlamp product, unless the prospective user has previously signed the risk acknowledgement certification within the preceding 6 months. The certification provides warnings regarding sunlamp products as well as information regarding the proper use of the devices. By making this information available to users in a direct and accessible manner, the certification would better enable consumers to make informed decisions about their use of sunlamp products. Moreover, and as discussed more fully in this section III.C, the information could counteract any false or misleading information that sunlamp product users may have received regarding the risks of indoor tanning.

Compliance with this proposed requirement would not be unduly burdensome for tanning facilities. The certification has already been drafted by FDA and, as discussed in the economic analysis in Docket FDA-2015-N-1765 and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> (Ref. 58), tanning facility operators would need only a brief amount of time to explain to the user the purpose of the certification and to process or file the signed certification. Reading and signing the certification would not be overly burdensome for prospective users—the user would need only a brief amount of time to read and sign the form, if they choose to proceed (Ref. 58).

FDA proposes that the text of the risk acknowledgement certification would have to be at least 10-point font and that the tanning facility operator would have to provide a copy of the signed acknowledgement certification to the prospective user and retain a copy of the signed acknowledgement certification for 1 year or until the prospective user signs a new risk acknowledgement certification, whichever is sooner. The statements in the certification are intended to inform prospective users of the risks they may be exposing themselves to by using the device and the inherent risks posed by UV radiation, as well as provide information regarding the proper use of the device.

When developing the certification, FDA aimed to inform readers of the most serious risks in a clear and succinct manner in order to promote rapid comprehension and not take more time than necessary for the key information to be conveyed and understood. Readability analysis, human participants' usability testing, and human factors/risk communication analysis were conducted on the certification to ensure the certification achieved its intended goals clearly and succinctly (Refs. 58 and 59). After obtaining feedback from the testing, the certification was revised consistent with recommendations made in the testing and is presented in this proposed rule with its refined content and format. FDA welcomes comment on the proposed certification form.

Unlike a label that must be affixed to a device (see § 878.4635(b)(6)(i)(A)), a risk acknowledgement certification can include more comprehensive warnings to ensure that users are aware of the risks associated with the use of the devices (Refs. 50 and 59). FDA expects that users will consider the risks carefully when signing the certification. If users were provided the certification but not required to sign it, they would be less likely to read the risk information in the certification, and they may even opt not to read the certification, mistakenly thinking that it was promotional material provided by the tanning facility.

Members of the 2010 Advisory Panel recommended that sunlamp product users be required to read and sign an acknowledgement of risks related to sunlamp products before using the device. Since this meeting, FDA has become aware of additional information regarding the use of sunlamp products that further supports the need for risk acknowledgement certifications.

There are reports in the literature that document tanning facility operators failing to inform patrons of certain risks, causing various groups to call for “informed consent” or better informing users at indoor tanning facilities (Ref. 60).

In keeping with the literature, on February 1, 2012, staff of the U.S. House of Representatives Committee on Energy and Commerce released a report summarizing their findings regarding false and misleading information provided to patrons of indoor tanning salons, especially teenage women. They found, for example, that 90 percent of operators responded that indoor tanning presented no risks (Ref. 61). When pressed about skin cancer specifically, more than half of the operators claimed indoor tanning would not increase the risk (Ref. 61). Some operators who did inform their patrons of skin cancer risks nevertheless mischaracterized the magnitude and the vulnerable subpopulations (Ref. 60). Other operators provided misleading benefit information, including claims that indoor tanning would protect patrons from cancer or beneficially create vitamin D (Ref. 61).

These reported practices support the need for risk acknowledgement certifications, which could counteract any false or misleading information communicated to prospective users. This risk acknowledgment will provide prospective users with accurate information about the risks and proper use of the devices so that they can make informed decisions about their use of these devices.

#### IV. Environmental Impact

The Agency has determined that under 21 CFR 25.34(f) this proposed action will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## V. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). OMB has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We believe this proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The proposed rule would restrict the use of sunlamp products to individuals aged 18 years and over and require all prospective users to read and sign a risk acknowledgement certification before use (unless the prospective user has previously signed the form within the preceding 6 months). The social benefits from this proposed rule stem from a potential reduction in the incidence of skin cancer. The social costs of the proposed rule are associated with the value of time spent by users and tanning facility operators on the risk acknowledgement certifications and verifying proof of age, as well as other compliance costs. As discussed more fully in the complete assessment, analyzing the impact of the proposed rule is difficult because of the uncertainty of how users would be affected by reading and signing the risk acknowledgment certification and how nonuse when under 18 years of age would affect later adult use. Because of this uncertainty, we use a 1 to 10 percent range in the response rate to the risk information and age restriction, assuming that the age restriction reduces future tanning. Under these scenarios, assuming a discount rate of 7 percent the annualized cost over 10 years would range from \$104 million to \$114 million; annualized benefits would range from \$70 to \$115 million. With a 3 percent discount rate the annualized cost over 10 years would range from \$122 million to \$144 million; annualized benefits would range from \$151 to \$248 million.

In addition to the social costs, the proposed rule would likely generate distribution effects from the reduced demand for tanning services. The annualized reduction in indoor tanning revenues would range from about \$500 million to \$820 million at a 7 percent discount rate over 10 years and from about \$500 million to \$825 million at a 3 percent discount rate.

Table 1—Summary of the Impact of the Proposed Rule

	<b>7% Discount rate, 5% impact</b>	<b>7% Discount rate, 1% impact</b>	<b>7% Discount rate, 10% impact</b>	<b>3% Discount rate, 5% impact</b>	<b>3% Discount rate, 1% impact</b>	<b>3% Discount rate, 10% impact</b>
Present Value over 10 Years						
Benefits	632.9	491.7	806.8	1,657.3	1,284.4	2,115.7
Costs	763.4	732.2	801.7	1,126.4	1,043.3	1,228.6
Net Benefits	-130.5	-240.5	5.1	530.9	241.1	887.1
Lost Revenue	4,532.9	3,527.2	5,770.4	5222.4	4287.4	7040.7
Annualized						

Value over 10 Years						
Benefits	90.1	70.0	114.9	194.3	150.6	248.0
Costs	107.2	104.2	114.1	132.1	122.3	144.0
Net Benefits	-18.6	-34.2	0.7	62.2	28.3	104.0
Revenue Loss	645.4	502.2	821.6	647.4	502.6	825.4

Tanning salons and most of the other establishments who offer commercial tanning services are classified as Other Personal Care Services under the North American Industry Classification System (NAICS 812199). We do not have information on the size distribution of this industry but most, if not all, entities are small businesses. There are 18,000 to 19,000 indoor tanning salons and 15,000 to 20,000 other facilities that offer indoor tanning services. The proposed rule would have a significant impact on a substantial number of small entities chiefly due to the loss of revenue.

The full assessment of the economic analysis is available in Docket FDA-2015-N-1765 and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> (Ref. 62). Table 2 summarizes the analysis.

Table 2—Summary of Benefits, Costs and Distributional Effects of the Proposed Rule

Category	Primary estimate	Low estimate	High estimate	Units	Year dollars	Discount rate(%)	Period covered(years)	Notes
Benefits:								
Annualized Monetized \$millions/year	\$90.10	\$70.00	\$114.90	2014	7	10		
	194.30	150.60	248.00	2014	3	10		
Annualized Quantified				2014	7	10		
				2014	3	10		
Qualitative								
Costs:								
Annualized	107.20	104.20	114.10	2014	7	10		
Monetized \$millions/year	132.10	122.30	144.00	2014	3	10		
Annualized				2014	7	10		
Quantified				2014	3	10		
Qualitative								
Transfers:								
Federal Annualized				2014	7	20		
Monetized \$millions/year				2014	3	20		
	From:	To:						
Other Annualized	645.4	502.2	821.6	2014	7	10		
Monetized \$millions/year	647.4	502.6	825.4	2014	3	10		
	From: Industry	To: Consumer						
Effects	This will have a significant impact on a substantial number of small entities.							

## VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to “construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain State requirements “different from or in addition to” certain Federal requirements applicable to devices (21 U.S.C. 360k; See *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)). This proposed rule creates a requirement under 21 U.S.C. 360k.

At the time of publication of this proposed rule, most States and some localities have acted to impose some form or restriction on tanning for minors. <sup>(3)</sup> Section 521(b) of the FD&C Act (21 U.S.C. 360k(b)) provides that the Commissioner of Food and Drugs may, upon application of a State or local government, exempt a requirement from preemption, if the State or local requirement for the device is more stringent than the requirement under the FD&C Act, or if the requirement is necessitated by compelling local conditions and compliance with it would not cause the device to be in violation of a requirement under the FD&C Act. Following this process, and if this rule becomes final, a State or local government may request an exemption from preemption for those State or local requirements pertaining to sunlamp products that are preempted by the Agency's final rule. FDA's rules that detail the content of such requests and the process for considering them are contained within 21 CFR part 808.

## VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions are shown in this section VII with an estimate of the annual recordkeeping. Included in the estimate is the time for maintaining documentation and disclosing materials.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Restricted sale, distribution, and use of sunlamp products.

*Description:* FDA is requesting OMB approval of the requirements set forth in this proposed rule, which would: (1) Restrict the use of sunlamp products to individuals age 18 years and over (§ 878.4635(c)(1)); (2) require that tanning facility operators provide a user manual to users and prospective users that request one, or the name and address of the manufacturer or distributor from who a user manual may be obtained (21 CFR 878.4635(c)(2)); (3) require that sunlamp product 510(k) holders accompany each product with a user manual and provide a user manual to users and tanning facility operators that request one (§ 878.4635(c)(3)); and (4) require all prospective users to read and sign a risk acknowledgement certification before use (unless the prospective user has previously signed the certification within the preceding 6 months) (§ 878.4635(c)(4)).

*Description of Respondents:* The requirements apply to manufacturers and distributors of sunlamp products, sunlamp product users and prospective users, as well as tanning facility operators.

*Burden:* FDA estimates the burden of this collection of information to be as follows:

Table 3—Estimated Annual Recordkeeping Burden <sup>1</sup>

Activity/21 CFR section	Number of recordkeepers	Number of records perrecordkeeper	Total annual records	Average burden perrecordkeeping	Total hours
Facility maintains signed certification (878.4635(c)(4)(iii))	36,000	594	21,384,000	0.004 (0.25 minutes, i.e., 15 seconds)	85,536

Table 4—Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs
<b>One-Time Burden</b>						
Facility explains certification on user's first visit	36,000	297	10,692,000	0.008 (30 seconds)	85,536	\$2,000,000
Manufacturer/Distributor provides user manual with device; provides copy of manual upon request (878.4635(c)(3))	20	1	20	15	300	27,800
<b>Total one-time burden</b>					<b>85,836</b>	<b>2,027,800</b>
<b>Annual Burden</b>						
Facility provides user manual upon request (878.4635(c)(2))	36,000	297	10,692,000	0.004 (0.25 minutes, i.e., 15 seconds)	42,768	

The economic analysis for this rulemaking provides a range of 33,000 to 39,000 for the number of tanning facilities (18,000 to 19,000 indoor tanning salons and 15,000 to 20,000 other facilities that offer indoor tanning services). In the PRA analysis we use the mean, 36,000 facilities, for the estimated number of facility-respondents. The economic analysis also provides a range for the number of sunlamp product users (after accounting for the impact of the age restriction and the communication of the risk information) of 10.2 to 11.2 million. We used the mean, 10.7 million, to calculate the average number of users per facility (10.7 million users divided by 36,000 facilities equals an average of 297 users per facility).

Proposed § 878.4635(c)(2) of the proposed rule would require, upon request by a user, tanning facility operators to supply a copy of the user manual for their sunlamp products; or the tanning facility could supply the name and address where the user could request a copy of the manual. We believe the incremental compliance costs to tanning facilities would be negligible because facilities receive the user manual with the equipment and likely already use the information to train their employees. Requests from users would not be frequent and the tanning facility need only supply the name and address, which could be an email address, of the 510(k) holder. We expect it will take approximately 15 seconds for the facility to provide the address.

Proposed § 878.4635(c)(3) of the proposed rule would require the 510(k) holders of sunlamp products to, upon request, supply tanning facility operators, users, and potential users copies of their user manuals. The 510(k) holders would have to develop standard operating procedures (SOPs) for responding to requests. In our experience, it would take a company about 5 hours of management time to develop the SOPs and set up a system for response. We believe most of the approximately 20 510(k) holders would satisfy this proposed requirement by making the manuals available on the Internet so recurring costs to satisfy requests for the user manual should be negligible. Many companies already make user manuals available online but for those who do not, it may take up to 10 hours of a computer programmer's time to modify the company's Web site and to upload the manuals for both current and past models that could still be in use. About 20 firms manufacture and distribute sunlamp products that could be affected by these proposed requirements. Because we do not know how many of them have user manuals online and all would have to modify their Web pages so product users could find the manuals, we are assuming all firms will incur one-time costs of 5 hours for SOPs and 10 hours to modify their Web pages. We include an estimate of \$27,800 for one-time capital costs to account for the wage rate for a manager and computer programmer.

Proposed § 878.4365(c)(4)(iii) would require tanning facilities to maintain signed risk acknowledgement certifications for at least 1 year or until the user signs a new risk acknowledgement certification, whichever is earlier. The 10.7 million users divided among the 36,000 tanning facilities yields an average of 297 users per facility and since users must sign the certification twice per year, this is 594 certifications to be maintained by each tanning facility per year. Multiplying the 594 certifications by the 36,000 facilities yields 21,384,000 total certifications to be filed per year. FDA expects that filing the certification, either paper or electronic, will take the facility 15 seconds or 0.004 hours and this multiplied by the 21,384,000 total certifications yields a burden estimate of 85,536 hours for this recordkeeping requirement. As mentioned previously, the number of facilities and users is an average based on the range of facilities and users stated in the economic analysis of this rulemaking. Therefore, the resulting hour burden is consistent with, but not identical to, the hours stated in the economic analysis.

We also assume that the first time a user visits a tanning facility after the date the proposed

requirements become effective, a tanning facility operator would take an extra 30 seconds to explain to the prospective user the purpose of the certification and the facility's policy regarding its implementation. We have therefore included a one-time burden estimate for facilities to explain the certification to users. As mentioned previously, the numbers of facilities and users are averages based on the ranges of facilities and users stated in the economic analysis of this rulemaking. Therefore, the resulting hour-burden is consistent with, but not identical to, the hours stated in the economic analysis. We estimate the one-time cost burden will be \$2 million, the mean of the range (\$1.9 to 2.1 million) stated in the economic analysis.

In addition, FDA concludes that the user's proof of age in § 878.4635(c)(1) and the risk acknowledgement certification in § 878.4635(c)(4) do not constitute information but are rather "Affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments . . ." (5 CFR 1320.3(h)(1)).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. To ensure that comments on information collection are received, OMB recommends that written comments be faxed or emailed (see ADDRESSES). These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

### VIII. Proposed Effective Date

FDA proposes that any final rule based on this proposal become effective 90 days after its date of publication in the Federal Register.

### IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and online at <http://www.regulations.gov> (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

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## List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

## Part 878 General and Plastic Surgery Devices

1. The authority citation for part 878 continues to read as follows:

### Authority

21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 878.4635 is amended as follows:

- a. Redesignate paragraph (c) as paragraph (d);
- b. Add new paragraph (c);
- c. Revise the heading of newly designated paragraph (d).

The revisions and additions read as follows:

§ 878.4635

Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

\* \* \* \* \*

(c) *Restrictions on sale, distribution, and use of sunlamp products.* (1) A tanning facility operator must not permit the use of a sunlamp product unless the prospective user is at least 18 years of age and has signed the risk acknowledgement certification described in paragraph (c)(4) of this section.

(2) A tanning facility operator must, upon request by a sunlamp product user or prospective user, with respect to any sunlamp product that the operator operates, provide a copy of the sunlamp product user manual or the name and address of the manufacturer or distributor from whom a user manual may be obtained.

(3) In addition to assuring that a user manual accompanies each sunlamp product, a 510(k) holder must provide, upon request, a copy of the sunlamp product user manual to any tanning facility operator, sunlamp product user, or prospective user with respect to any sunlamp product it manufactures/manufactured or distributes/distributed.

(4) *Risk acknowledgement certification.* (i) The tanning facility operator must not permit the use of a sunlamp product unless it obtains each prospective user's signature on a risk acknowledgement certification that contains the following statement prior to use of the sunlamp

product, unless the prospective user has previously signed the risk acknowledgement certification within the preceding 6 months:

BILLING CODE 4164-01-P



(ii) The text of the risk acknowledgement certification shall be at least 10-point font.

(iii) The tanning facility operator shall provide a copy of the signed acknowledgement certification to the prospective user and the tanning facility shall retain a copy of the signed risk acknowledgement certification for 1 year or until the prospective user signs a new risk acknowledgement certification, whichever is earlier.

(d) *Electronic product performance standard.* \* \* \*

Dated: December 16, 2015.

Leslie Kux,  
Associate Commissioner for Policy.

[FR Doc. 2015-32024 Filed 12-18-15; 8:45 am]

BILLING CODE 4164-01-C

## Footnotes

(1) UV emitting lamps that are medical devices and have different intended uses than devices classified under 21 CFR 878.4635 (intended to tan skin) would not fall under that regulation. Manufacturers of such devices would have to obtain approval, clearance or authorization to market their device under the premarket approval, 510(k) or *de novo* pathway. The use of such devices in a pediatric population is beyond the scope of this document.

(2) See

<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/ucm205684.htm>.

(3) National Conference of State Legislators, Indoor Tanning Restrictions for Minors—A State-by-State Comparison, <http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx> (last updated July 1, 2015).

**PR Sunlamp Products; Proposed Amendment to Performance Standard**

This Proposed Rule document was issued by the **Food and Drug Administration (FDA)**

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Due Mar 21 2016, at 11:59 PM ET

**Action**

Proposed rule.

**Summary**

The Food and Drug Administration (FDA or Agency) is proposing to amend the performance standard for sunlamp products and ultraviolet (UV) lamps intended for use in these products. This standard was last amended in 1985. The current amendments seek to improve consumer safety by requiring more effective communication regarding the risks posed by these products. They also would reduce risks to consumers by updating technical requirements to reflect current science, and by adopting and incorporating by reference certain elements from the International Electrotechnical Commission (IEC) International Standard 60335-2-27, Ed. 5.0: 2009-12.

**Dates**

Submit either electronic or written comments on the proposed rule by March 21, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by January 21, 2016.

**Addresses**

You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-1998-N-0880 for "Sunlamp Products; Proposed Amendment to Performance Standard." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the title, "Sunlamp Products; Proposed Amendment to Performance Standard."

**For Further Information Contact**

Sharon Miller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4234, Silver Spring, MD 20993-0002, 301-796-2471.

**Supplementary Information**

**ID:** FDA-1998-N-0880-0004

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**Date Posted:** Dec 22, 2015

**CFR:** 21 CFR Parts 1002 and 1040

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**Comments**

**11**  
Comments Received\*

*If you live in an area that does not get enough sunlight during some months (such as the northern US), UV products can be an important way to get enough vitamin...*  
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*Please prevent young people from having access to these products*  
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*As a teen tanner in Indiana, I was already affected by the under 16 ban. Now sixteen and tanning, another ban will not stop me. What's to stop a minor of any...*  
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**Docket Information**

*This document is contained in*  
[FDA-1998-N-0880](#)

**Related Dockets:** None

**Related RINs:** None

**Related Documents:**

- [See FDA-1998-N-0880-0001 re Pre\\_FDMS-1](#)
- [Medical Devices: Sunlamp Products Performance Standard...](#)

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## Executive Summary

### Purpose of the Regulatory Action

The Safe Medical Devices Act of 1990 (Pub. L. 101-629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602) from Title III of the Public Health Service Act to Chapter V, subchapter C of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360hh *et seq.*). Under these provisions, FDA administers an electronic product radiation control program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products.

A sunlamp product is a device that emits UV radiation to induce tanning. The device incorporates one or more UV lamps as a radiation source. Examples of sunlamp products are tanning beds, which are used while lying down, and tanning booths, which are used while standing. UV radiation-emitting products not used for tanning would not be affected by this proposed rule. Devices emitting UV radiation to treat dermatological disorders are regulated separately and are not part of this proposed rule. As electronic products, sunlamp products are subject to the regulations for electronic product radiation control, including parts 1000 to 1010 (21 CFR parts 1000 through 1010) and § 1040.20 (21 CFR 1040.20).

Sunlamp products emit UV radiation to induce tanning. The adverse effects of UV radiation are well known. UV radiation can cause acute injuries such as sunburns and eye irritations (*e.g.*, photokeratitis). Long-term UV exposure has been associated with skin cancer (including squamous cell carcinoma, basal cell carcinoma, and melanoma), skin aging, and cataracts. Epidemiological studies of the effects of UV radiation on incidence of cancer and other health problems are complicated by latency between exposure and disease, difficulty controlling for environmental exposure to UV radiation, and other factors. Nevertheless, a recent meta-analysis found an increase in the risk of melanoma for each additional session of sunlamp product use per year (Ref. 1).

FDA is concerned about the safety risks from UV radiation. Therefore, FDA is updating our requirements for sunlamp products which allow for indoor exposure to UV radiation. There have been many changes in our understanding of how UV radiation interacts with human skin since FDA published the document entitled "Sunlamp Products; Performance Standard" in the Federal Register of September 6, 1985 (50 FR 36548). There have also been many changes in the indoor tanning industry which affect the type of equipment on the market and the measurement techniques used by manufacturers. FDA is updating requirements for sunlamp products to bring our regulations up to date with current science. FDA also wants to improve consumers' understanding of the risks related to UV radiation exposure.

### Summary of the Major Provisions of the Regulatory Action in Question

The objective of this proposed rule is to align the performance standards for sunlamp products with current scientific knowledge and our understanding of how these products are used. This proposed rule seeks to facilitate compliance, improve awareness among operators and consumers about risks of use, and ultimately improve public health.

FDA proposes to incorporate certain elements of the International Electrotechnical Commission (IEC) International Standard 60335-2-27, Ed. 5.0: 2009-12, "Household and Similar Electrical Appliances—Safety—Part 2-27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation," by reference. Harmonizing the FDA standard with the current IEC standard would bring it up to date with current science and better protect consumers from the risks posed by these devices. Harmonization would have benefits for sunlamp product manufacturers as well. Currently, many firms producing sunlamp products for sale within the United States and abroad have to follow both IEC and FDA standards. Aligning these standards would mean that such firms would need to comply with a single set of rules instead of two different ones, at least for the particular clauses which are being adopted and incorporated by reference.

FDA proposes to amend the requirements of part 1002 as specified in table 1 to require that manufacturers of UV lamps intended to be used in sunlamp products are subject to the same record and reporting requirements as manufacturers of sunlamp products. FDA wants to ensure that all test data necessary to ensure compliance with § 1040.20 are collected and maintained. Currently, manufacturers of UV lamps are required to submit only product reports. Under proposed § 1002.1, manufacturers of UV lamps would also be required to submit supplemental reports and annual reports and to maintain test records and distribution records. Moreover, proposed § 1002.1 would also require that manufacturers of protective eyewear maintain test records demonstrating that the eyewear complies with applicable UV and visible transmittance requirements as well as distribution records. In addition, proposed § 1002.1 would also require that manufacturers of protective eyewear submit annual reports, supplemental reports, and product reports to FDA.

Proposed § 1040.20(c)(1) would set an absolute limit for UVC radiation. An absolute limit on UVC (200-290 nanometer (nm)) irradiance would provide greater assurance of user safety because a ratio permits higher doses of UVC (as long as they correspond to higher doses in the 260 to 320 nm range). UVC, which is not present in sunlight that reaches the Earth's surface, is potentially harmful to users while less effective for tanning than UVA or UVB. FDA has chosen not to adopt the limit for UVC radiation in Ed. 5.0 of IEC 60335-2-27 because this limit is 10 times lower than the limit in Ed. 4.2 and FDA believes that it would be difficult for some manufacturers to measure irradiance at this level.

Proposed § 1040.20(c)(2)(ii) would limit the maximum timer interval to one that would result in a biologically effective (also referred to as erythral-effective) dose that would not exceed 500 joules/meter<sup>2</sup> (J/m<sup>2</sup>) which is approximately equivalent to the 624 J/m<sup>2</sup> value (weighted with the CIE LYTLE action spectrum) that was specified in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule. FDA has determined that a dose of 500 J/m<sup>2</sup> (weighted with the CIE erythral action spectrum) provides a biologically equivalent dose that is more closely matched to the current 624 J/m<sup>2</sup> value than does the IEC dose limit of 600 J/m<sup>2</sup>.

Proposed § 1040.20(c)(3) would add a requirement that the control enabling manual termination of radiation emission (sometimes referred to as the "panic button" or "emergency stop") be easily accessible and readily identifiable to the user. This would ensure that users could easily turn the sunlamp product off for any reason.

Proposed § 1040.20(c)(4)(ii) would expand application of the performance requirements to all protective eyewear intended to be used with sunlamp products, whether sold together with a sunlamp product or sold separately. UV wavelengths can cause serious eye damage, and exposure to the shorter wavelength region of the UV spectrum is especially dangerous. The spectral transmittance requirements for protective eyewear are necessary to protect users of sunlamp products from these risks, which directly result from the UV radiation emitted by the sunlamp product.

Proposed § 1040.20(d)(1)(i) would modify the warning statement required to appear on the label of all sunlamp products. FDA believes that the current warning statement is too long, not user-friendly, and that its content and format could be improved to more effectively communicate the risks of indoor tanning to users. Based on its analysis of the consumer testing, FDA concluded that the current warning statement could be made more effective by changing its required language, formatting, and location. FDA believes that the proposed warning statement would most effectively convey the risks of indoor tanning to users.

The proposed rule would also improve user safety by adopting the IEC's "equivalency code" system for ensuring compatibility between sunlamp products (*e.g.*, tanning beds and booths) and the UV lamps that are used in them. Proposed § 1040.20(d)(1)(vi) would require the label of all sunlamp products to indicate the equivalency code range of the UV lamp to be used in the sunlamp product. Proposed § 1040.20(d)(2)(ii) would require the label of each UV lamp to indicate its UV lamp equivalency code. FDA believes the adoption of the IEC's absolute rating system for replacement UV lamps would eliminate confusion regarding proper lamp replacement, facilitate the enforcement of lamp compatibility requirements, and improve the safety of sunlamp products.

Proposed § 1040.20(d)(3) would retain the requirement of the current FDA standard that the required label information must be legible and readily accessible to view by a sunlamp product user immediately prior to use. Proposed § 1040.20(d)(3)(i) would incorporate specifications into the rule regarding the location, spacing, and font of the required warning statement. FDA believes that these label specifications would

information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. This can result in discrepancies between this count and those displayed when conducting searches on the Public Submission document type. For specific information about an agency's public submission policy, refer to its website or the Federal Register document.

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ensure that users see the required warning prior to use, and would result in a more comprehensive and effective standard.

Proposed § 1040.20(e)(3) would add a requirement for the provision of the required warning statement in all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale. This requirement would ensure that consumers are fully informed of the risks presented by sunlamp products at the time they consider purchasing it.

Proposed § 1040.20(g) is also modeled after the proposed FDA Performance Standard for Laser Products (78 FR 37723, June 24, 2013). FDA believes the addition of these requirements, which have been used successfully over the past two decades for laser products, would improve safety by ensuring that modifications that affect performance would be held to the same standards as original manufacturing.

#### Costs and Benefits

Estimated one-time costs are \$20,917 to \$113,240 and annual costs are \$4,686 to \$7,230. The present discounted costs are \$57,181 to \$151,390 at 7 percent and \$61,498 to \$165,883 at 3 percent. Annualized at 7 percent over 10 years, total costs are \$8,141 to \$21,498. At 3 percent, annualized total costs are \$7,867 to \$19,447.

The primary benefit of the proposed rule would be from reduced injuries, including sunburn, photokeratitis, skin cancer, cataracts and ocular melanoma, and from reduced exposure to UV radiation. We are unable to quantify the benefits, but where possible, demonstrate that they satisfy breakeven tests using very conservative assumptions. The benefits of this proposed rule would justify the costs.

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### I. Background

The Safe Medical Devices Act of 1990 (Pub. L. 101-629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602) from Title III of the Public Health Service Act to Chapter V, subchapter C of the FD&C Act (21 U.S.C. 360hh *et seq.*). Under these provisions, FDA administers an electronic product radiation control program to protect the public health and safety. This authority provides for developing, amending, and administering radiation safety performance standards for electronic products, including sunlamp products.

Until recently, sunlamp products intended for tanning were class I medical devices and exempt from premarket notification requirements, subject to the limitation in 21 CFR 878.9 (see 53 FR 23856, June 24, 1988; 59 FR 63005, December 7, 1994). On March 25, 2010, FDA held a meeting of the General and Plastic Surgery Devices Panel of the FDA/Center for Devices and Radiological Health (CDRH) Medical Devices Advisory committee to seek input on whether the classification or regulatory controls needed to be changed. For a summary of this meeting, see <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM206522.pdf>. On June 2, 2014, based on the panel's recommendations, among other things, FDA reclassified UV lamps intended to tan the skin from class I and exempt from premarket notification to class II and subject to premarket notification, and renamed them sunlamp products and UV lamps intended for use in sunlamp products (see 21 CFR 878.4635; 79 FR 31205, June 2, 2014).

As electronic products, sunlamp products are subject to the regulations for electronic product radiation control, including parts 1000 through 1010 and § 1040.20. The sunlamp products performance standard in § 1040.20 was originally published in the Federal Register on November 9, 1979 (44 FR 65352). In the Federal Register of September 6, 1985 (50 FR 36548), FDA amended § 1040.20 and made it applicable to all sunlamp products manufactured on or after September 8, 1986.

FDA also issued several policy letters pertaining to specific aspects of its regulation of sunlamp products. On June 25, 1985, FDA issued a policy letter entitled "Policy on Warning Label Required on Sunlamp Products" (available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf>) (Ref. 2). This document pertained to the location, spacing, and legibility of the required warning label. On August 21, 1986, FDA issued a policy letter entitled "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products" (available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf>) (Ref. 3). This document explained the criteria FDA uses to evaluate the adequacy of the exposure schedule and the recommended maximum exposure time for sunlamp products. On September 2, 1986, FDA issued another policy letter entitled "Policy on Lamp Compatibility," (available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095325.pdf>) (Ref. 4). This document listed the criteria FDA uses to evaluate appropriate replacement lamps for sunlamp products.

Before prescribing any electronic product performance standards, FDA is required to consult a statutory advisory committee, the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). See section 534(f)(1)(A) of the FD&C Act (21 U.S.C. 360kk(f)(1)(A)). At the September 23 and 24, 1998, meeting of TEPRSSC, FDA presented general concepts for amendments to the performance standard for sunlamp products, which are embodied in this proposed rule. The committee recommended that FDA pursue development of the amendments.

On February 9, 1999, CDRH published an Advance Notice of Proposed Rulemaking (ANPRM) (Docket No. 98N-1170), 64 FR 6288 (February 9, 1999), for the following reasons:

1. FDA was concerned that inadequate attention was being given to recommended exposure schedules, which are designed to minimize consumer risk.
2. FDA was concerned that the warnings for sunlamp products were not reaching many users of sunlamp products prior to their purchase and use, and that purchasers may not be aware of the risks associated with UV exposure from sunlamp products.
3. Sunlamp products technology has changed since the FDA Performance Standard was amended in 1985. These changes can affect both the intensity and spectral characteristics of the UV emission from sunlamps.
4. Because there is no uniform grading/rating system, choosing a replacement lamp can be confusing for sunlamp product owners and tanning facilities. It also makes the job of tanning facility inspectors more difficult because they cannot easily verify whether the correct lamps are installed in the sunlamp products. The use of incorrect replacement lamps can lead to sunburns.

The specific amendments under consideration were as follows:

1. Harmonizing the sunlamp product performance standard with IEC Standard 60335-2-27;
2. Revising and updating the August 21, 1986, guidance entitled "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products," and incorporating the updated guidance into the sunlamp product performance standard;
3. Adding a provision clarifying that "manufacturing" under the FD&C Act includes a modification of a sunlamp product that affects any aspect of its performance or intended function for which § 1040.20 has an applicable requirement;
4. Updating the warning statement required by § 1040.20(d)(1)(i) to simplify the wording and to highlight the risk of developing skin cancers;
5. Requiring reproduction of the text of the warning statement specified in § 1040.20(d)(1)(i) in catalogs, specification sheets, and brochures; and
6. Developing a biological efficacy rating scale for UV lamps intended for use in sunlamp products to simplify appropriate lamp replacement.

In response to this ANPRM, FDA received 26 comments from State and local radiation control agencies, manufacturers, the American Academy of Dermatology, the Skin Cancer Foundation, an industry educational association, a tanning facility owner, and a trade organization. FDA considered these comments in developing this proposal.

FDA presented recommendations for amendments to the sunlamp performance standard to TEPRSSC on June 21, 2000. FDA explained to TEPRSSC that it was prepared to move forward with some of the amendments at that time, but did not have sufficient scientific data to move forward with the lamp classification or the exposure schedule amendment. TEPRSSC advised FDA to develop scientifically-based exposure schedule guidelines before incorporating these requirements into the Performance Standard itself. FDA scientists obtained special funding from FDA's Office of Women's Health to conduct this research. Upon completion, FDA presented guidelines for exposure schedules to the IEC TC (Technical Committee) 61, MT (Maintenance Team) 16 that is responsible for developing standards for these products. The IEC accepted these guidelines and incorporated them into IEC 60335-2-27 standard (Ed. 5.0), which published on December 14, 2009.

In February 2002, FDA held a 2-day meeting with the indoor tanning industry and representatives from the U.S. Army Environmental Hygiene Agency, Health Canada, the Swedish Radiation Protection Institute, and the North Carolina Department of Radiation Protection. The purpose of this meeting was to solicit input from the affected parties on the lamp equivalence issue and other possible amendments to the FDA Performance Standard for Sunlamp Products, which we considered in the development of this proposed rule.

The IEC TC 61, MT 16 committee met in October 2002, and decided to work with IEC SC (subcommittee) 34A to develop practical standardized test methods and a classification scheme for low-pressure, fluorescent tanning lamps to facilitate replacement of these lamps when they wear out. IEC SC 34A has responsibility for the IEC 61228 standard entitled "Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method" (Ref. 5). At their meeting in 2003, IEC TC 61, MT 16 and IEC SC 34A reached a consensus position on lamp testing and classification. This position has now been incorporated into the IEC 60335-2-27, Ed. 5.0 standard (Ref. 6) and the IEC 61228, Ed. 2.0 standard (Ref. 5).

In October 2003, FDA presented six amendments to TEPRSSC and all were approved with modifications to two of the proposals. These six amendments, along with others, are being presented in this proposed rule and are outlined in section II.

In addition, FDA has informed radiological health representatives from the states of our intentions to amend the Sunlamp Products Performance Standard through semi-annual meetings with the state Conference of Radiation Control Program Directors. See Web site at <http://www.crcpd.org/>.

FDA is concerned about the safety risks from UV radiation. Therefore, FDA is updating our requirements for sunlamp products—which allow for indoor exposure to UV radiation.

FDA is undertaking three initiatives to address the risks associated with sunlamp products. First, in a final reclassification order that issued June 2, 2014 (79 FR 31205 at 31213), FDA reclassified sunlamp products and UV lamps intended for use in sunlamp products from class I to class II, and established special controls and premarket notification (510(k)) requirements under the medical device authorities of the FD&C Act. The special controls include performance testing and labeling requirements, including a warning that sunlamp products are not to be used on persons under the age of 18 years.

Second, and simultaneously with this proposed rule, FDA is proposing device restrictions under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), which authorizes FDA to issue regulations imposing restrictions on the sale, distribution or use of a device, if, because of its potentiality for harmful effects or the collateral measures necessary to its use, FDA determines that absent such restrictions, there cannot be a reasonable assurance of its safety and effectiveness. As explained elsewhere in this issue of the Federal Register, the proposed device restrictions would require that:

1. Tanning facility operators permit use of sunlamp products only if the prospective user is age 18 or older;
2. Tanning facility operators, upon request by the user or prospective user, provide a copy of the sunlamp product user manual or name and address of the manufacturer or distributor from whom a user manual may be obtained;
3. 510(k) holders assure that a user manual accompanies each sunlamp product and, upon request, provide a copy of the user manual to any tanning facility operator, user or prospective user; and
4. Tanning facility operators obtain each prospective user's signature on a risk acknowledgement certification before use that states that they have been informed of the risks to health that may result from use of these devices.

These device restrictions would primarily apply to tanning facility operators, and to a lesser extent, device manufacturers and distributors. FDA would not consider people who use their own tanning beds (home users) to be tanning facility operators.

Finally, in this action, FDA is proposing amendments to the sunlamp products and UV lamps performance standard at § 1040.20 (21 CFR

1040.20) (last updated in 1985), which includes technical and labeling requirements issued under the radiological health provisions of the FD&C Act. FDA is taking this action to reflect current scientific knowledge related to sunlamp product use, harmonize it more closely with IEC International Standard 60335-2-27, Ed. 5.0: 2009-12, and strengthen the warning statement required by § 1040.20(d)(1)(i) in accordance with the results of the study FDA conducted under section 230 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85).

## II. Contents of the Proposed Regulation

### A. Overview

This preamble will focus on the proposed changes to § 1002.1 and § 1040.20, which include:

- Requiring that UV lamp manufacturers follow the same reporting requirements as sunlamp product manufacturers,
- Requiring that protective eyewear manufacturers maintain distribution records and test records relating to the UV and visible transmittance of the eyewear as well as requiring the submission of annual reports, supplemental reports, and product reports to FDA,
- Changing the content, format, and location of the required warning statement to make it more effective at communicating the risks of indoor tanning to consumers,
- Replacing the current limit on the ratio of UVC to UVB irradiance with an absolute limit on UVC irradiance,
- Limiting the maximum timer interval to one that would not exceed a maximum dose of 500 J/m<sup>2</sup>, weighted with the CIE Reference Action Spectrum for Erythema (1999),
- Adopting the IEC “equivalency code” system for labeling and measuring the strength of replacement lamps to prevent original lamps being replaced with more powerful lamps, which can lead to sunburn,
- Changing the current subjective requirement regarding the visible transmittance of protective eyewear to an objective, quantitative requirement, adopted from the IEC standard,
- Adding a cap on the amount of visible transmittance allowed through the protective eyewear, to protect the users' retina from intense visible light,
- Updating the guidelines for the required manufacturer-recommended exposure schedule, by requiring conformity to the IEC standard, which is based on current science,
- Requiring that a reproduction of the warning label be provided in all catalogs, specification sheets, brochures, and consumer-directed Web pages on which sunlamp products are offered for sale, and
- Requiring that persons involved in significant modification of sunlamp products re-certify the product just as the manufacturer of a new product would. This requirement currently exists in the FDA Laser Standard (21 CFR 1040.10(i)).

### B. Changes to § 1002.1

FDA proposes to amend the requirements of part 1002 as specified in table 1 to require that manufacturers of UV lamps intended to be used in sunlamp products are subject to the same record and reporting requirements as manufacturers of sunlamp products. When table 1 was first codified, it was common for the manufacturers of UV lamps to be the same entity that manufactured the sunlamp product. Today, the market has changed and there are some manufacturers that manufacture only UV lamps. FDA wants to ensure that all test data necessary to ensure compliance with § 1040.20 are collected and maintained. Currently, manufacturers of UV lamps are required to submit only product reports. Under proposed § 1002.1, manufacturers of UV lamps would also be required to submit supplemental reports and annual reports and to maintain test records and distribution records. In addition, manufacturers of protective eyewear would also need to maintain distribution records as well as test records demonstrating that the eyewear complies with applicable UV and visible transmittance requirements. Proposed § 1002.1 would also require that manufacturers of protective eyewear submit annual reports, supplemental reports, and product reports to FDA.

### C. Changes to § 1040.20

#### 1. INCORPORATION BY REFERENCE

FDA proposes to incorporate certain elements of the IEC International Standard 60335-2-27, Ed. 5.0: 2009-12 entitled “Household and Similar Electrical Appliances—Safety—Part 2-27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation,” by reference (Ref. 6). See proposed § 1040.20(a)(2). A similar approach has been used successfully with the FDA standard for laser products, § 1040.10, see FDA Guidance, “Laser Products—Conformance With IEC 60825-1 and IEC 60601-2-22” (Ref. 7), and FDA has proposed to incorporate by reference several provisions of IEC 60825-1, Ed. 2, into the laser products performance standard (78 FR 37723). Harmonizing the FDA standard with the current IEC standard would bring it up to date with current science and better protect consumers from the risks posed by these devices. FDA has representation on the IEC committee and has had significant influence on changes made to the IEC standard over the past decade. Working with this committee, which includes representatives from industry, government, and the medical community, has provided FDA with useful expertise and perspectives to which it may not otherwise have access.

Harmonization would have benefits for sunlamp product manufacturers as well. Currently, many firms producing sunlamp products for sale within the United States and abroad have to follow both IEC and FDA standards. Aligning these standards would mean that such firms would need to comply with a single set of rules instead of two different ones, at least for the particular clauses which are being adopted and incorporated by reference.

#### 2. DEFINITIONS

“Protective goggles” would be added to the definition of “protective eyewear” in proposed § 1040.20(b) since this is the synonymous term used in the IEC standard.

The definition of “sunlamp product” would be amended to make clear that tanning beds and tanning booths are included within this term.

We propose adding a definition for “tanning course.” This term is used in Annex DD of IEC 60335-2-27, Ed. 5.0, to aid the manufacturer in the development of its exposure schedule. In the context of exposure schedules, “tanning course” means the period of time over which a tan is developed, starting with the first short exposure and building up to longer exposures over time, usually requiring a period of 3 to 4 weeks. In an effort to ensure that a useful recommendation is provided to the user about maximum annual exposure, this concept is utilized in the exposure schedule requirements at proposed § 1040.20(d)(1)(iv) and the example exposure schedule provided therein. FDA is uncertain how users might best keep track of their exposure over many weeks and months, and is particularly interested in comments on the best approach for informing users about limiting their annual exposure.

#### 3. PERFORMANCE REQUIREMENTS

Proposed § 1040.20(c)(1) would set the irradiance limit for UVC radiation (200-290 nm) at 0.03 Watts/meter<sup>2</sup> (W/m<sup>2</sup>) at the shortest recommended exposure distance from the sunlamp product. This limit is the same as the one in the previous version of IEC 60335-2-27 (Ed. 4.2: 2007-04). This requirement would replace the current limit on the ratio of irradiance in the 200 to 260 nm wavelength range to the irradiance in the 260 to 320 nm wavelength range (see § 1040.20(c)(1)). One of the comments received in response to the 1999 ANPRM recommended that the current ratio limit in § 1040.20(c)(1) be dropped since it is no longer necessary, considering current low-pressure lamp technology, and because a limit on the UVC/UVB ratio provides less safety than an absolute limit on the UVC emissions from a sunlamp product. FDA agrees with this comment. An absolute limit on UVC (200-290 nm) irradiance would provide greater assurance of user safety because a ratio permits higher doses of UVC (as long as they correspond to higher doses in the 260 to 320 nm range). UVC, which is not present in sunlight that reaches the Earth's surface, is potentially harmful to users while less effective for tanning than UVA or UVB. FDA has chosen not to adopt the limit for UVC radiation in Ed. 5.0 of IEC 60335-2-27 because this limit is 10 times lower than the limit in Ed. 4.2 and FDA believes that it would be difficult for some manufacturers to measure irradiance at this level. FDA is particularly interested in

comments on this proposal.

FDA proposes to change § 1040.20(c)(2) by adding a dose-based limit similar to the one in FDA's 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3) to the maximum timer interval requirement in paragraph (c)(2)(ii). FDA also proposes to remove paragraph (v) from § 1040.20(c)(2).

Proposed § 1040.20(c)(2)(ii) would incorporate by reference the action spectrum used in figure 103 of IEC 60335-2-27, Ed. 5.0 for calculating the effective dose that defines the maximum timer interval. This method uses the internationally-accepted CIE Reference Action Spectrum for Erythema (Ref. 8) instead of the CIE LYTLE action spectrum that was defined in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3). Since 1986, the CIE Action Spectrum for Erythema has been verified and accepted by research laboratories across the globe. As a result, it is used worldwide in the calculation of the UV Index.

The 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule also recommends the use of the Parrish 1982 melanogenesis action spectrum, in addition to the CIE LYTLE erythema action spectrum, as a secondary means of calculating the maximum timer interval. As it has been found that the two action spectra are highly correlated, this calculation does not provide independent characterization data and the requirement is redundant. Therefore, proposed § 1040.20(c)(2)(ii) would not require a second calculation of the maximum timer interval.

Proposed § 1040.20(c)(2)(ii) would limit the maximum timer interval to one that would result in a biologically-effective (also referred to as erythema-effective) dose that would not exceed  $500 \text{ J/m}^2$ , which is approximately equivalent to the  $624 \text{ J/m}^2$  value (weighted with the CIE LYTLE action spectrum) that was specified in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3). Although the FDA would like to harmonize its standard as much as possible with the IEC standard, consumer safety is our main concern. Based on spectral irradiance data submitted to the Agency and on data presented at the 2004 Commission Internationale de l'Éclairage (CIE) Symposium on "Light and Health: Non-visual effects" (Ref. 10), FDA has determined that a dose of  $500 \text{ J/m}^2$  (weighted with the CIE erythema action spectrum) provides a biologically-equivalent dose that is more closely matched to the current  $624 \text{ J/m}^2$  value than does the IEC dose limit of  $600 \text{ J/m}^2$ . FDA invites comment on this proposal.

Proposed § 1040.20(c)(3) would add a requirement that the control enabling manual termination of radiation emission (sometimes referred to as the "panic button" or "emergency stop") be easily accessible and readily identifiable to the user. This would ensure that users can easily turn the sunlamp product off for any reason.

Proposed § 1040.20(c)(4)(ii) would expand application of the performance requirements to all protective eyewear intended to be used with sunlamp products, whether sold together with a sunlamp product or sold separately. As we have previously explained, UV wavelengths can cause serious eye damage, and exposure to the shorter wavelength region of the UV spectrum is especially dangerous. (See 42 FR 65189 at 65191, December 30, 1977.) Short-term risks include photokeratitis, which is very painful and causes temporary loss of vision, and there is also a risk of retinal damage from short-term or long-term exposure, which could cause blind spots to form in the retina. Repeated, long-term UV exposure increases the risk of cataracts, and there is evidence of an association between UV exposure and ocular melanoma (Ref. 11).

The spectral transmittance requirements for protective eyewear are necessary to protect users of sunlamp products from these risks, which directly result from the UV radiation emitted by the sunlamp product. Users of sunlamp products, especially those who tan in tanning facilities, often use protective eyewear manufactured by an entity other than the manufacturer of the sunlamp product. Use of sunlamp products with eyewear that does not meet these requirements would increase the risk posed by the radiation emitted by the sunlamp product and undermine the protection provided by the performance standard. Therefore it is necessary to apply the standard to all protective eyewear intended to be used with sunlamp products.

The proposal would also modify the protective eyewear transmittance requirements of § 1040.20(c)(4)(ii) to better ensure user safety and achieve harmony with the IEC standard. (See clause 32.102 of IEC 60335-2-27, Ed. 5.0.) The requirements for spectral transmittance in the UV range of 200-400 nm would remain the same as in the current FDA standard. The proposed rule would adopt the limit of 5 percent on the visible transmittance in the range of 400-550 nm from clause 32.102 of the IEC standard. This requirement would provide additional safety to protect the retina from intense visible light. Currently, there is no such requirement included in the FDA standard. The proposed rule would abandon the current requirement that spectral transmittance shall be sufficient over the wavelength range greater than 400 nm to provide visibility to the user, and instead adopt the lower limit of 1 percent on luminous transmission from clause 32.102 of the IEC standard. Replacing the subjective standard with an objective one would make compliance easier to verify and improve uniformity and consistency.

#### 4. LABEL REQUIREMENTS

Proposed § 1040.20(d)(1)(i) would modify the warning statement required to appear on the label of all sunlamp products. FDA believes that the current warning statement is too long, not user-friendly, and that its content and format could be improved to more effectively communicate the risks of indoor tanning to users. As discussed in section I, FDA has been considering updating the required warning since 1999. In 2007, Congress required FDA to conduct consumer focus group testing to evaluate the adequacy of sunlamp product warning labels in conveying certain risk information to consumers, including the risk of skin cancer. (See section 230 of the Food and Drug Administration Amendments Act of 2007, Pub. L. 110-85.) Based on its analysis of the consumer testing, FDA concluded that the current warning statement could be made more effective by changing its required language, formatting, and location. See the FDA Report to Congress entitled "Labeling Information on the Relationship Between the Use of Indoor Tanning Devices and Development of Skin Cancer or Other Skin Damage" (Ref. 12).

FDA would like to harmonize its standard as much as possible with the IEC 60335-2-27 Ed. 5.0 standard. However, based on the results of the focus group testing, we believe it is appropriate for some differences to remain between the FDA warning statement and the IEC warning statement, especially since the IEC warning statement provides only the general substance to be conveyed (since it is intended for use in multiple languages) and does not provide formatting specifications. FDA believes that the proposed warning statement would most effectively convey the risks of indoor tanning to users. Specifically, the label of each sunlamp product would have to contain a warning statement with the following language and format:

"DANGER—Ultraviolet Radiation (UV)

UV can cause:

- Skin Cancer
- Skin Burns
- Premature Skin Aging such as wrinkles and age spots
- Eye Damage (both short- and long-term)

Wear FDA-compliant protective eyewear to prevent eye damage, such as burns or cataracts.

Follow the recommended exposure schedule to avoid severe skin burns.

Talk to your doctor or pharmacist before tanning if you use medicines and/or cosmetics. Some of these products can make you more sensitive to skin and eye damage from UV."

Currently, § 1040.20(d)(1)(iv) requires sunlamp product labels to include a recommended exposure schedule containing certain information. FDA proposes to add a requirement that the exposure schedule be developed in accordance with the specific parameters in IEC 60335-2-

27, Ed. 5.0, Annex DD, which would be incorporated by reference. The proposed rule provides an example of a recommended exposure schedule that would meet the guidelines/parameters in IEC 60335-2-27, Ed. 5.0, Annex DD. See proposed § 1040.20(d)(1)(iv). These parameters are different from those provided in the 1986 FDA Policy Letter on Maximum Timer Interval and Exposure Schedule (Ref. 3), and are based on current science, including recent human research conducted at FDA. This requirement is aimed at reducing the cumulative UV dose to sunlamp product users and attaining closer harmonization of FDA and the IEC standard.

Proposed § 1040.20(d)(1)(iv) would also require a warning to appear either directly above or below the exposure schedule stating "Skin Type I individuals (always burns, never tans) should never use sunlamp products." This warning is based on years of published research showing that Skin Type I individuals sunburn easily and cannot tan and are therefore at the greatest risk for skin cancer. By "Skin Type" we are referring to the historical Fitzpatrick skin typing system (Ref. 13) developed in 1975 by dermatologist Thomas Fitzpatrick to predict skin reactivity in phototherapy. Under this categorization scheme, Skin Type I is the fairest and most sensitive while Skin Type VI is the darkest and least sensitive to UV radiation. The Skin Types that are most likely to tan through the use of sunlamp products are Skin Types II through IV. It has been shown (Ref. 14) that Skin Types III and IV can attain a tan with UV doses that are similar to what is needed for Skin Type II. Thus, the same dose can be used to develop and maintain a tan for all three Skin Types. This was confirmed in clinical studies performed at FDA (Ref. 15). This is a change from the approach of the 1986 Policy Letter, which called for exposure schedules to be differentiated by Skin Type.

The proposed rule would also improve user safety by adopting the IEC's "equivalency code" system for ensuring compatibility between sunlamp products (e.g., tanning beds and booths) and the UV lamps (sometimes referred to as light bulbs) that are used in them. Proposed § 1040.20(d)(1)(vi) would require the label of all sunlamp products to indicate the equivalency code range of the UV lamp to be used in the sunlamp product. The equivalency code range would have to be determined in accordance with clause 22.111 and Annex CC of IEC 60335-2-27, Ed. 5.0, which would be incorporated by reference. Proposed § 1040.20(d)(2)(ii) would require the label of each UV lamp to indicate its UV lamp equivalency code, as defined in Annex CC of IEC 60335-2-27, Ed. 5.0. In determining the "UV code" component of the UV lamp equivalency code, output would have to be measured in accordance with IEC 61228, Ed. 2.0, "Fluorescent Ultraviolet Lamps used for Tanning—Measurement and Specification Method," (Ref. 5) which would be incorporated by reference.

FDA believes the adoption of the IEC's absolute rating system for replacement lamps would eliminate confusion regarding proper lamp replacement, facilitate the enforcement of lamp compatibility requirements, and improve the safety of sunlamp products. Currently, FDA relies on a relative system in which the lamp manufacturer has to provide to FDA and to users a list of lamps with which the manufacturer's lamp is compatible. (See §§ 1002.10 and 1040.20(e)(2)(iii).) As new lamp manufacturers and new lamp models enter the marketplace, while other manufacturers abandon old models of lamps or leave the marketplace, it is increasingly cumbersome to keep track of which lamps are compatible with the lamps originally provided with the sunlamp product. This can cause confusion for tanning facility owners, FDA, and State or local inspectors. When incorrect lamps are used as replacements, the erythema-effective intensity may be greater, resulting in burns. Therefore, FDA has decided that an absolute rating system is needed, which would require that a code be printed on the lamp to indicate its erythema-effective output, and a code range be printed on the sunlamp product, to indicate which lamps to use with it. Another advantage of adopting the provisions in both of these IEC standards is that they provide detailed measurement specifications, which would ensure consistency among manufacturers.

Proposed § 1040.20(d)(3) would retain the requirement of the current FDA standard that the required label information must be legible and readily accessible to view by a sunlamp product user immediately prior to use. FDA provided details regarding compliance with this requirement in its June 25, 1985, policy letter entitled "Policy on Warning Label Required on Sunlamp Products" (Ref. 2). Proposed § 1040.20(d)(3)(i) would incorporate similar specifications into the rule regarding the location, spacing, and font of the required warning statement. The proposal specifies that the warning statement would have to be readily accessible to view whether the tanning bed canopy or tanning booth door is open or closed when the user approaches, which may necessitate that it appear in more than one location on the sunlamp product. FDA believes that these label specifications would ensure that users see the required warning prior to use, and would result in a more comprehensive and effective standard.

Proposed § 1040.20(d)(3)(ii) specifies that required UV lamp information would have to appear on the packaging of the lamp in addition to being permanently affixed or inscribed on the lamp itself. This would ensure that anyone replacing a UV lamp would be aware of the lamp equivalency code and required warnings before and after purchase.

We propose revising § 1040.20(d)(3)(iv) to achieve consistency with the requirement in the device labeling regulations at 21 CFR 801.15(c) (1) that all words, statements, and other information required by or under authority of the FD&C Act to appear on the label or labeling of a device must appear in the English language (or a foreign language for articles distributed solely in Puerto Rico or in a Territory where the predominant language is not English). Since the labeling of UV lamps must comply with the labeling requirements of part 801 and § 1040.20, we propose to remove the language in § 1040.20(d)(3)(iv) that permits the manufacturer to express the manufacturer's name and month and year of manufacture as code or symbols. FDA is not aware of any request to use symbols or codes for this purpose in the past.

## 5. USER INFORMATION

The proposal would remove § 1040.20(e)(1)(iv) since the recommended exposure schedule no longer needs to be differentiated by skin type and would be required to be prominently displayed at the beginning of the users' instructions under proposed § 1040.20(e)(1)(i).

Proposed § 1040.20(e)(1)(v) would add a requirement for the provision of instructions and warnings regarding assembly, operation, and maintenance, which is modeled on the proposed FDA Performance Standard for Laser Products (78 FR 37723). This would better protect individuals who assemble, test, and maintain sunlamp products.

Proposed § 1040.20(e)(3) would add a requirement for the provision of the required warning statement in all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale. This requirement would ensure that consumers are fully informed of the risks presented by sunlamp products at the time they consider purchasing it.

## 6. TEST FOR DETERMINATION OF COMPLIANCE

Proposed § 1040.20(f) would add a requirement that the performance requirements for the measuring instrument in clause 32.101 of IEC 60335-2-27 Ed. 5.0 would apply.

## 7. MODIFICATION OF CERTIFIED SUNLAMP PRODUCTS

Proposed § 1040.20(g) is also modeled after the proposed FDA Performance Standard for Laser Products (78 FR 37723). FDA believes the addition of these requirements, which have been used successfully over the past 2 decades for laser products, would improve safety by ensuring that modifications that affect performance would be held to the same standards as original manufacturing.

## III. Legal Authority

Section 532 of the FD&C Act (21 U.S.C. 360ii) authorizes FDA to establish and administer an electronic product radiation control program to protect the public health and safety. Section 534 of the FD&C Act gives FDA authority to issue regulations establishing performance standards for electronic products to control their emission of radiation. These standards may include requirements for product testing and radiation measurement, the attachment of warning signs and labels, and the provision of instructions for product installation, operation, and use. Section 1003(b)(2)(E) of the FD&C Act (21 U.S.C. 393(b)(2)(E)) requires FDA to ensure that public health and safety are protected from electronic product radiation. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

Section 230 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85) directed FDA to determine whether changes to the warning statement would more effectively communicate the risks of indoor tanning, such as skin cancer, and to submit a report that

includes an explanation of the measures being implemented to significantly reduce the risks associated with indoor tanning devices. As explained in section II, based on consumer testing, FDA determined that the proposed warning statement would better communicate the risks of indoor tanning to consumers, and is proposing these amendments to the sunlamp products performance standard to significantly reduce the risks associated with these products.

#### IV. Proposed Effective Date

FDA proposes that any final rule issued based on this proposal become effective 1 year after the date of publication of the final rule in the Federal Register.

#### V. Environmental Impact, No Significant Impact

The Agency has determined under 21 CFR 25.34(c) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environment impact statement is required.

#### VI. Economic Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. We do not believe this proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain so we are explicitly seeking comment on the impacts.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

The proposed rule would affect several aspects of the performance standards to reduce risks associated with use. The costs are summarized in table 1. Estimated one-time costs are \$20,917 to \$113,240 and annual costs are \$4,686 to \$7,230. The present discounted costs are \$57,181 to \$151,390 at 7 percent and \$61,498 to \$165,883 at 3 percent. Annualized at 7 percent over 10 years, total costs are \$8,141 to \$21,498. At 3 percent, annualized total costs are \$7,867 to \$19,447.

The primary benefit of the proposed rule would be from reduced injuries, including sunburn, photokeratitis, skin cancer, cataracts and ocular melanoma and from reduced exposure to UV radiation. We are unable to quantify the benefits, but demonstrate that they satisfy breakeven tests using very conservative assumptions. The benefits of this proposed rule would justify the costs.

Table 1—Present Discounted Costs of the Proposed Rule

Year	Low cost scenario	High cost scenario
Discounted @7 percent	\$57,181	\$151,390
Discounted @3 percent	61,498	165,883
10-Year Annualized @7 percent	8,141	21,498
10-Year Annualized @3 percent	7,867	19,447

The full assessment of the economic analysis is available in Docket FDA-1998-N-0880 and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> (Ref. 16).

#### VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to "construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision at section 542 of the FD&C Act (21 U.S.C. 360ss) that preempts the States from establishing, or continuing in effect, any standard with respect to an electronic product which is applicable to the same aspect of product performance as a Federal standard prescribed under section 534 of the FD&C Act and which is not identical to the Federal standard. If this proposed rule is made final, the final rule would prescribe a Federal standard under section 534 of the FD&C Act. However, section 542 of the FD&C Act does not "prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard." (Section 542 of the FD&C Act.)

#### VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in the paragraphs that follow with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Sunlamp Products; Proposed Amendment to § 1002.1 (Record and Reporting Requirements) and § 1040.20 (Performance Standard).

*Description:* The Safe Medical Devices Act of 1990 (Pub. L. 101-629) transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602) from Title III of the Public Health Service Act (42 U.S.C. 201 *et seq.*) to Chapter V, subchapter C of the FD&C Act (21 U.S.C. 301 *et seq.*). Under the FD&C Act, FDA administers an electronic product radiation control program to protect the public health and safety. FDA also develops and administers radiation safety performance standards for electronic products, including sunlamp products.

Current § 1002.1 requires that sunlamp product manufacturers submit product reports, supplemental reports, and annual reports and requires that test records and distribution records are maintained, used for summary data submitted in the annual report, and made available upon request. In addition, current § 1002.1 requires UV lamp manufacturers to submit product reports. Proposed § 1002.1 would require that

manufacturers of UV lamps also submit supplemental reports and annual reports and maintain test records and distribution records.

Proposed § 1002.1 would also require that manufacturers of protective eyewear maintain test records and distribution records as well as submit annual reports, supplemental reports, and product reports. The eyewear must meet certain transmittance limits in the UV and visible wavelength range. Both manufacturers of sunlamp products that include eyewear with their products and manufacturers of protective eyewear that is sold separately would be responsible for maintaining records of the results yielded by the testing and reporting these results to FDA. (See § 1002.1.) There are no operating and maintenance costs associated with testing the eyewear because this requirement reflects current market practices.

Proposed § 1040.20(d)(2)(ii) would require that the UV lamp labeling include a replacement lamp code instead of a list of compatible replacement lamps. Although the single UV lamp manufacturer in the United States is already required to conduct spectral irradiance testing of lamps in order to demonstrate compatibility with other model lamps (whether made by that company or other manufacturers), proposed § 1040.20(d)(2)(ii) would require testing in accordance with test methods as specified in IEC 61228, Ed. 2.0, "Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method." The spectral irradiance data obtained is used to calculate the UV code that would be required to be printed on the lamp by proposed § 1040.20(d)(2)(ii). Manufacturers would be responsible for maintaining and reporting records of the results yielded by the testing as well as imprinting the lamp with the replacement lamp code.

Proposed § 1040.20(d)(2)(iii) would require that each UV lamp have a label containing the model identification of the lamp, if applicable. Manufacturers would be responsible for printing the model number on the lamp itself.

Proposed § 1040.20(d)(3)(iii) would permit the manufacturer of the sunlamp product or UV lamp to submit a request to the Director, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health for an approval of alternate labeling if the size, configuration, design, or function of the sunlamp product or UV lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective. In these circumstances, manufacturers would be responsible for reporting the request to FDA. The operating and maintenance costs associated with this provision are based on correspondence costs (postage) for non-email communications.

Proposed § 1040.20(d)(3)(iv) would permit manufacturers of UV lamps to permanently affix or inscribe the tags or labels required by §§ 1010.2(b) and 1010.3(a) on the lamp packaging associated with the UV lamps, rather than the UV lamps themselves. The third party disclosure burden of this provision would be the time it takes to inscribe the label or tag on the UV lamp packaging.

Proposed § 1040.20(e)(1)(v) would require instructions for sunlamp "assembly, operation, and maintenance," and would include a schedule of maintenance. This information would also protect those maintaining and assembling sunlamp products from inadvertent exposure to UV radiation by providing adequate instructions to avoid UV exposure during assembly or maintenance. We presume that the maintenance schedules would be developed from known information about how to properly maintain these devices. The third party disclosure burden of this provision would be the time spent bringing this known information into a user-friendly format and disclosing it to users. We also assume that this information would be identical for all units of a given model of sunlamp products.

Proposed § 1040.20(g) would require that those who change the function or performance characteristics of a sunlamp are manufacturers and would need to recertify and re-identify the device. This requirement applies only if the modification affects any aspect of the product's performance or intended function(s) for which § 1040.20 has an applicable requirement. We believe some sunlamp owners (e.g., tanning facility owners) view such modifications as a less expensive alternative to purchasing a new sunlamp product. We believe some owners, otherwise inclined to alter their sunlamp's performance characteristics, would be deterred from doing so by our proposal because recertification would cost a tanning facility owner more than \$30,000 in operating and maintenance costs since tanning facility owners do not typically have the equipment necessary to recertify sunlamp products. However, if a tanning facility owner chooses to recertify the sunlamp product, documentation must be submitted to FDA.

*Description of Respondents:* Respondents for these information collections are manufacturers of sunlamp products and UV lamps intended for use in sunlamp products, and manufacturers of protective eyewear that is intended to be used with sunlamp products.

FDA estimates the burden of this collection of information as follows:

Table 2—Estimated Annual Reporting Burden

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital and operating and maintenance costs
1002.1(b) —Lamp only	1	9	9	2	18	
1002.1(b) — Protective eyewear	5	4	20	0.5	10	
1040.20(d)(2)(ii)	1	1	1	1	1	
1040.20(d)(3)(iii)	1	1	1	.17	.17 (10 minutes)	
1040.20(g)	1	1	1	8	8	\$43,000
Total					37	\$43,000

Table 3—Estimated Annual Recordkeeping Burden

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Capital and operating and maintenance costs
1002.1(b) —Lamp only	1	2	2	2.5	5	
1002.1(b) — Protective eyewear	5	3	15	7	105	
1040.20(d)(2)(ii)	1	75	75	0.8	60	\$30,000
Total					170	\$30,000

Table 4—Estimated Annual Third Party Disclosure Burden <sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1040.20(d)(1)(vi)	5	5,200	26,000	.0034	88
1040.20(d)(2)(ii)	1	286,000	286,000	.0017	486
1040.20(d)(2)(iii)	1	286,000	286,000	.0017	486
1040.20(d)(3)(ii)	1	286,000	286,000	.0017	486
1040.20(d)(3)(iv)	1	23,833	23,833	.0017	41
1040.20(e)(1)(v)	5	10	50	12	600
Total					2,187

#### A. Reporting Burden

For § 1002.1(b)—Lamp only, we estimate the single U.S.-based manufacturer of UV lamps would need to submit 2 new types of reports (supplemental reports and an annual report) for the 75 models. Based on previous submissions, we estimate that nine supplemental reports would be submitted per year. Annual reports are submitted once per year. We estimate that it takes approximately 2 hours to complete each report for a total of 18 burden hours.

For § 1002.1(b)—Protective eyewear, we estimate that the five respondents would need to report the information annually and that each of the manufacturers produces two models of protective eyewear. Manufacturers are not required to produce two types of eyewear; however, FDA estimates that each of the five respondents produces two types of eyewear that could be made available with sunlamp products. Manufacturers would fill out and submit the annual, supplemental, and product reports demonstrating conformance to the performance standard, and this process is estimated to take 30 minutes per report for a total of 10 hours.

For § 1040.20(d)(2)(ii), we estimate that the single U.S.-based manufacturer of UV lamps would test 75 UV lamps and that the time needed to incorporate the data into the product report is 1 hour.

For § 1040.20(d)(3)(iii), we estimate that one sunlamp product and UV lamp manufacturer would submit a request for alternate labeling approval to FDA. This task is expected to be performed by clerical staff that prepare the request and submit it to FDA. This process is expected to take 10 minutes (.17 hours) to type the request and email it. The request is expected to be submitted electronically and does not involve any operating and maintenance cost.

For § 1040.20(g), we estimate that, at most, one respondent per year would decide to re-certify a sunlamp product with the Agency, instead of the less expensive alternative of purchasing a new sunlamp product. The \$43,000 capital costs for recertifying the sunlamp product includes the required instrumentation and calibration light sources such as a double-grating spectroradiometer with integrating sphere and software. We estimate the time needed to make the necessary spectral measurements and compile them into a report that would be sent to FDA to take 8 hours.

#### B. Recordkeeping Burden

For § 1002.1(b)—Lamp only, we estimate the single U.S.-based manufacturer of UV lamps would need to maintain 2 types of records (test records and distribution records) for each of the 75 models and that it takes approximately 2 minutes per model per record for a total of 300 minutes, or 5 burden hours.

For § 1002.1(b)—Protective eyewear, we estimate that there are five U.S. manufacturers of protective eyewear that would be affected by this amendment. However, this number is uncertain and we welcome comment on this issue. We estimate that each of the manufacturers produces 2 models of protective eyewear and the manufacturer would sample approximately 10 units per model. The time required to perform the necessary testing, including time to verify the instrument, set up the test and prepare and file a report takes approximately 7 hours per model. Protective eyewear manufacturers would also be required to maintain distribution records for their products. We estimate that 7 hours per year would be necessary for the manufacturer to log and file the distribution data. We estimate a total of 105 hours for each manufacturer to maintain the single distribution record for both models of protective eyewear as well as perform the testing for the individual test records that are to be maintained for each model of protective eyewear.

For § 1040.20(d)(2)(ii), we expect that the single U.S.-based lamp manufacturer does not use IEC UV codes and would have to test and label its models under the proposed rule. The manufacturer has an estimated 30 to 120 models and we chose the mean number of models (75) for our calculations. The mean cost of testing each model is \$350 and the cost for an ink stamp is \$50 per model, yielding an approximate \$30,000 in operating and maintenance cost for § 1040.20(d)(2)(ii). Manufacturers are already performing similar spectral irradiance testing to determine lamp compatibility. We estimate that it would take 0.8 hours per model to modify the test setup to measure spectral irradiance in order to determine the UV code as well as file the results, for a total of 60 hours. We estimate that the single U.S.-based lamp manufacturer is already maintaining records of these tests, so there should be no additional cost associated with proposed § 1002.1 that requires lamp manufacturers now also to maintain test records, although FDA is seeking comment on this understanding.

#### C. Third Party Disclosure Burden

For § 1040.20(d)(1)(vi), we estimate that the five respondents would need to list the code range that can be used in each of the 5,200 sunlamp products produced annually. We estimate 2 minutes to print and affix this label on each the 26,000 sunlamp products, for a total of 88 hours.

For § 1040.20(d)(2)(ii), the single U.S.-based lamp manufacturer would need to inscribe the UV lamp equivalency code onto each lamp. We estimate it would take 1 minute to ink stamp 10 lamps with the new UV lamp equivalency code. The operating and maintenance costs for this information collection are subsumed in the recordkeeping burden estimate for § 1040.20(d)(2)(ii). The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take approximately 28,600 minutes per year, or about 486 hours.

For § 1040.20(d)(2)(iii), the single U.S.-based lamp manufacturer would need to inscribe the model identification onto each lamp. We estimate it would take 1 minute to ink stamp ten lamps with the model identifier. The operating and maintenance costs for this information collection are subsumed in the recordkeeping burden estimate for § 1040.20(d)(2)(ii). The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take approximately 28,600 minutes per year, or about 486 hours.

For § 1040.20(d)(3)(iv), we estimate that the single U.S.-based lamp manufacturer would permanently affix or inscribe the tags or labels required by §§ 1010.2(b) and 1010.3(a) on the packaging of all the UV lamps rather than the lamps themselves. Since lamps are typically packaged and sold in cases of 12, this yields 23,833 packages that must bear the third party disclosure required by § 1040.20(d)(3)(iv). We estimate it would take 1 minute to ink stamp 10 lamp packages with the tags or labels required by §§ 1010.2(b) and 1010.3(a) for a total of 41 hours.

For § 1040.20(d)(3)(ii), the single U.S.-based lamp manufacturer would need to inscribe or affix the UV lamp equivalency code on the packaging of each lamp. We estimate it would take 1 minute to ink stamp 10 lamp packages with the new UV lamp equivalency code. The lamp manufacturer produces 286,000 new lamps per year so this process is expected to take 28,600 minutes per year, or about 486 hours.

For § 1040.20(e)(1)(v), we estimate the 5 respondents would need to go through this reporting exercise once for each of their 10 models of sunlamp products. We estimate that 10 hours of a technician's time would be required to collect all the necessary information regarding maintenance and assembly and 2 hours of a manager's time to review this information once it is re-formatted into the user instructions. Thus, we estimate a total of 12 hours per model of sunlamp product would be required for a total of 600 hours. This would be a one-time cost.

This proposed rule also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information found in proposed § 1040.20(d)(1)(ii); (d)(1)(iii); (d)(1)(iv), 1st sentence; (d)(1)(v); (e)(1)(i) to (e)(1)(iv); (e)(2)(i), and (e)(2)(ii) have been approved under OMB control number 0910-0025 (expires January 1, 2017); the collections of information found in § 1040.20(d)(3)(v) have been approved under OMB control number 0910-0485 (expires February 28, 2015).

In addition, FDA concludes that proposed § 1040.20(d)(1)(i); (d)(1)(iv), 2nd and 3rd sentences; (d)(2)(i); (d)(2)(iv); (d)(3)(i); and (e)(3) do not constitute "collection[s] of information" under the PRA. Rather, the labeling statements are "public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public." (5 CFR 1320.3(c)(2).)

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES). All comments should be identified with the title "Sunlamp Products; Proposed Amendment to § 1002.1 (Record and Reporting Requirements) and § 1040.20 (Performance Standard)."

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the Federal Register.

## IX. Incorporation by Reference

FDA is proposing to incorporate by reference certain portions of the IEC International Standards 60335-2-27, Ed. 5.0: 2009-12 entitled "Household and Similar Electrical Appliances—Safety—Part 2-27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation"; and 61228, Ed. 2.0, "Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method." You may purchase a copy of these materials from the International Electrotechnical Commission (IEC Central Office), 3 rue de Varembe, CH-1211 Geneva 20, Switzerland, call +41 22-919-02-11, <https://webstore.iec.ch/>. FDA is also proposing to incorporate by reference the American National Standard C81.10-1976, entitled "Specifications for Electric Lamp Bases and Holders—Screw-Shell Types." You may purchase a copy of the material from the American National Standards Institute, 1889 L St. NW., 11th Floor, Washington, DC 20036, call 202-293-8020, [www.ansi.org](http://www.ansi.org).

The IEC 60335 standard describes technical specifications that address the safety of electrical appliances that incorporate emitters for exposing the skin to UV and infrared radiation, including those found in tanning salons or other facilities. The IEC 61228 standard describes the method to measure, evaluate, and specify the characteristics of fluorescent UV lamps that are used in appliances for tanning purposes. The ANSI standard describes technical specifications that will help ensure only appropriate bulbs can be fitted to the appliance.

## X. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). FDA is explicitly seeking comment on how the proposed requirements would impact small entities.

Comments on the following two proposals listed are of special interest to FDA:

1. The Use of the Limit on UVC Irradiance of 0.03 W/cm<sup>2</sup> in IEC 60335-2-27, Ed. 4.2: 2007-4 Instead of the Limit of 0.003 W/cm<sup>2</sup> in IEC 60335-2-27, Ed. 5.0: 2009-12.
2. The Use of a Limit of 500 J/m<sup>2</sup> on the Maximum Dose Used to Calculate the Maximum Timer Limit, Instead of the 600 J/m<sup>2</sup> Limit in IEC 60335-2-27, Ed. 5.0: 2009-12.

## XI. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

1. Boniol, M., P. Autier, P. Boyle, and S. Gandini, "Cutaneous Melanoma Attributable to Sunbed Use: Systematic Review and Meta-analysis," *British Medical Journal*, 345:e8503, December 2012.
2. FDA, Policy on Warning Label Required on Sunlamp Products, Department of Health and Human Services, Center for Devices and Radiological Health, Rockville, MD, June 25, 1985, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095333.pdf>.
3. FDA, Policy on Maximum Timer Intervals and Exposure Schedule for Sunlamps, Department of Health and Human Services, Center for Devices and Radiological Health, Rockville, MD, August 21, 1986, <http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/HomeBusinessandEntertainment/UCM192707.pdf>.
4. FDA, Policy on Lamp Compatibility, Department of Health and Human Services, Center for Devices and Radiological Health, Rockville, MD, September 2, 1986, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095325.pdf>.
5. IEC 61228, Ed. 2.0, "Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method," IEC, Geneva, Switzerland.
6. IEC 60335-2-27, Ed. 5.0, "Household and Similar Electrical Appliances—Safety—Part 2-27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation," IEC, Geneva, Switzerland, 2009.
7. FDA Guidance for Industry and FDA Staff, "Laser Products—Conformance With IEC 60825-1 and IEC 60601-2-22 (Laser Notice No. 50)," June 24, 2007, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094366.pdf>.
8. CIE S 007/E-1998/ISO 17166: 1999(E) Erythral Reference Action Spectrum and Standard Erythema Dose, CIE Vienna, Austria.
9. "Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph," FDA, Department of Health and Human Services, 64 FR 27666, May 21, 1999.
10. Dowdy, J.C. and R.M. Sayre, "Comparison of IEC and U.S. FDA Sunlamp Standards: Critical Discrepancies in Exposure Timers and Annual Exposure Limits," Proceedings of the CIE Symposium 2004 on Light and Health: Non-Visual Effects, Vienna, Austria, pp. 183-188.
11. Vajdic, C.M., A. Kricger, M. Giblin, et al, "Sun Exposure Predicts Risk of Ocular Melanoma in Australia," *International Journal of*

12. FDA, "Report to Congress: Labeling Information on the Relationship Between the Use of Indoor Tanning Devices and Development of Skin Cancer or Other Skin Damage," submitted December 2008, available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109288.htm>.

13. Fitzpatrick, T.B., "The Validity and Practicality of Sun-Reactive Skin Type I Through VI," *Archives of Dermatology*, 124: 869-871, 1988.

14. Pathak, M.A. and D.L. Faselow, "Photobiology of Melanin Pigmentation: Dose/Response of Skin to Sunlight and its Contents," *Journal of the American Academy of Dermatology*, 9: 724-733, 1983.

15. Miller, S.A., S.G. Coelho, S.W. Miller, et al., "Evidence for a New Paradigm for UV Exposure: A Universal Schedule That is Skin Phototype-Independent," *Photoderm Photolmm Photomed*, 28: 187-195, 2012.

16. <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

## List of Subjects

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

Electronic products, Incorporation by reference, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 1002 and 1040 be amended as follows:

## Part 1002 Records and Reports

1. The authority citation for part 1002 is revised to read as follows:

### Authority

21 U.S.C. 352, 360, 360i, 360j, 360hh-360ss, 371, 374, 393.

2. Section 1002.1 is amended by revising Table 1 to read as follows:

§ 1002.1

Applicability.

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Table 1—Record and Reporting Requirements by Product

Manufacturer	Products	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a) <sup>1</sup>	Distribution records § 1002.30(b) <sup>2</sup>	Dealer and distributor
DIAGNOSTIC X-RAY <sup>3</sup> (§§ 1020.30, 1020.31, 1020.32, and 1020.33):								
Computed tomography	X	X		X	X	X	X	
X-ray system <sup>4</sup>	X	X		X	X	X	X	
Tube housing assembly	X	X		X	X	X		
X-ray control	X	X		X	X	X	X	
X-ray high voltage generator	X	X		X	X	X	X	
X-ray table or cradle			X		X	X	X	
X-ray film changer			X		X	X		
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X		X	X	X	
Beam-limiting devices	X	X		X	X	X	X	
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X	X	X	X	
Cephalometric devices manufactured after February 25, 1978			X		X	X		
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978			X		X	X	X	
CABINET X RAY								

(§ 1020.40):

Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY:							
Medical			X	X	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (§ 1020.10):							
<25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr IRLC 56			X	X <sup>6</sup>			
≥25kV and <0.1mR/hr IRLC 5 <sup>5</sup>	X	X		X			
≥0.1mR/hr IRLC 5 <sup>5</sup>	X	X		X	X	X	
MICROWAVE/RF:							
MW ovens (§ 1030.10)	X	X		X	X	X	
MW diathermy			X				
MW heating, drying, security systems			X				
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2-500 megahertz)			X				
OPTICAL:							
Phototherapy products	X	X					
Laser products (§§ 1040.10 and 1040.11)							
Class I lasers and products containing such lasers <sup>7</sup>	X			X	X		
Class I laser products containing class IIa, II, IIIa, lasers <sup>7</sup>	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers <sup>7</sup>	X	X		X	X	X	X
Class IIIb and IV lasers and products containing such lasers <sup>7</sup>	X	X		X	X	X	X
Sunlamp products (§ 1040.20)							
Lamps only	X	X		X	X	X	
Sunlamp products	X	X		X	X	X	X
Protective eyewear	X	X		X	X	X	
Mercury vapor lamps (§ 1040.30)							
T lamps	X	X		X			
R lamps			X				
ACOUSTIC:							

Ultrasonic therapy (§ 1050.10)	X	X	X	X	X	X
Diagnostic ultrasound					X	
Medical ultrasound other than therapy or diagnostic	X	X				
Nonmedical ultrasound					X	

## Part 1040 Performance Standards for Light Emitting Products

1. The authority citation for 21 CFR part 1040 is revised to read as follows:

### Authority

21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381, 393.

2. Section 1040.20 is revised to read as follows:

#### § 1040.20

Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

(a) *Applicability.* The provisions of this section, as amended, are applicable as specified to all sunlamp products and ultraviolet lamps intended for use in sunlamp products not later than [A DATE WILL BE ADDED 1 YEAR AFTER DATE OF PUBLICATION OF A FUTURE FINAL RULE IN THE Federal Register].

(b) *Definitions.* As used in this section, the following definitions apply:

*Exposure position* means any position, distance, orientation, or location relative to the radiating surfaces of the sunlamp product at which the user is intended to be exposed to ultraviolet radiation from the sunlamp product, as recommended by the manufacturer.

*Irradiance* means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter ( $W/cm^2$ ).

*Maximum exposure time ( $T_e$ )* means the greatest continuous exposure time interval recommended by the manufacturer of the sunlamp product.

*Maximum timer interval* means the greatest time interval setting on the timer of a sunlamp product.

*Protective eyewear or protective goggles* means any device designed to be worn by users of a sunlamp product to reduce exposure of the eyes to radiation emitted by the product.

*Spectral irradiance ( $E_\lambda$ )* means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ( $W/(cm^2/nm)$ ).

*Spectral transmittance ( $T_\lambda$ )* means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.

*Sunlamp product* means any device designed to incorporate one or more ultraviolet lamps intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning. This definition includes tanning beds and tanning booths.

*Tanning course* means a consecutive series of tanning exposures until a tan is developed, usually spanning a period of 3 to 4 weeks.

*Timer* means any device incorporated into a sunlamp product that terminates radiation emission after a preset time interval.

*Ultraviolet lamp* means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any sunlamp product.

(c) *Performance requirements—(1) UVC (200-290 nm) irradiance.* The total irradiance emitted by a sunlamp product in the wavelength range between 200 and 290 nm (UVC) shall not exceed  $0.03 W/m^2$ . UVC irradiance shall be measured at the shortest exposure distance recommended by the manufacturer, as required to be provided on the label of the sunlamp product by paragraph (d)(1)(ii) of this section. UVC irradiance shall be calculated using the following formula:



Where:

E is the total irradiance over the wavelength range of interest

$E_\lambda$  is the spectral irradiance in  $W/(m^2 \cdot nm)$

$\Delta_\lambda$  is the wavelength interval (nm).

The wavelength interval shall be 1 nm or less.

(2) *Timer system.* (i) Each sunlamp product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label information required by paragraph (e) of this section.

(ii) The maximum timer interval may not exceed the manufacturer's recommended maximum exposure time ( $T_e$ ) that is indicated on the label, as required by paragraph (d)(1)(iv) of this section. In addition, the maximum timer interval shall not result in a biologically-effective dose that exceeds  $500 J/m^2$ , weighted with the erythema action spectrum provided in figure 103 of IEC 60335-2-27, Ed. 5.0, which is incorporated by reference. The manufacturer's recommended maximum exposure time ( $T_e$ ) shall be determined using the following formula:



Where:

$S_{\lambda}$  is the erythema action spectrum in figure 103 of IEC 60335-2-27, Ed. 5.0

$E_{\lambda}$  is the spectral irradiance in  $W/(m^2 \cdot nm)$

$\Delta_{\lambda}$  is the wavelength interval (nm).

The wavelength interval shall be 1 nm or less.

(iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the sunlamp product.

(iv) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the sunlamp product has been prematurely terminated.

(3) *Control for termination of radiation emission.* Each sunlamp product shall incorporate a control on the product to enable the person being exposed to manually terminate radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp. This control shall be easily accessible to the user and be readily identified by touch and sight.

(4) *Protective eyewear.* (i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of all protective eyewear intended to be used with the sunlamp product shall not exceed a value of 0.001 over the wavelength range of greater than 200 nm through 320 nm, shall not exceed a value of 0.01 over the wavelength range of greater than 320 nm through 400 nm, and shall not exceed a value of 0.05 over the wavelength range of greater than 400 nm through 550 nm. In order to ensure adequate visibility through the protective eyewear, the luminous transmittance shall not be less than 1.0 percent. Spectral transmittance and luminous transmittance must be measured in accordance with clause 32.102 of IEC 60335-2-27, Ed. 5.0, which is incorporated by reference.

(5) *Compatibility of lamps.* An ultraviolet lamp shall not be capable of insertion and operation in either the "single-contact medium screw" or the "double-contact medium screw" lampholders described in C81.10-1976, which is incorporated by reference.

(d) *Label requirements.* In addition to the labeling requirements in part 801 of this chapter and the certification and identification requirements of §§ 1010.2 and 1010.3 of this chapter, each sunlamp product and ultraviolet lamp is subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1) *Labels for sunlamp products.* Each sunlamp product shall have labels which contain:

(i) A warning statement with the following language and format:



(ii) Exposure position(s) that may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) The manufacturer's recommended exposure schedule, including maximum exposure times per session, and overall maximum exposure time, in minutes, and spacing of sequential exposures. This schedule, with the following exceptions, must be developed in accordance with Annex DD of IEC 60335-2-27, Ed. 5.0, which is incorporated by reference.:

(A) The maximum single dose (which corresponds to the maximum timer interval at 1040.20(c)(2)(ii)) is  $500 J/m^2$  (not  $600 J/m^2$  as stated in Annex DD).

(B) Information regarding the maximum number of exposures per year must be based on a maximum yearly dose of  $15 kJ/m^2$ , weighted according to the erythema action spectrum shown in figure 103 of IEC 60335-2-27, Ed. 5.0.

(C) The exposure schedule must also include the following warning: "Skin Type I individuals (always burns, never tans) should never use sunlamp products." The exposure schedule must also include the statement: "Maximum sessions per week = 2."

(D) *Example schedule.* For a sunlamp product whose maximum exposure time ( $T_e$ ) = 20 minutes, the following table provides an example of what the exposure schedule might look like where a single tanning course covers a 4-week period:

Manufacturer-Recommended Exposure Schedule								
Maximum exposure time must not exceed 20 minutes								
Session #								
1	2	3	4	5	6	7	8	
Minutes (maximum) per session								
4	6	8	10	13	16	20	20	
Minimum time between exposures = 48 hours								
Maximum sessions per week = 2    Maximum tanning courses per year = 6								
Skin Type I individuals (always burns, never tans) should never use sunlamp products								

(v) A statement indicating the time it may take before the expected results appear.

(vi) The designation of the ultraviolet lamp equivalency code range to be used in the sunlamp product as defined in Clause 22.111 and Annex CC of IEC 60335-2-27, Ed. 5.0, which is incorporated by reference.

(2) *Labels for ultraviolet lamps.* Each ultraviolet lamp shall have a label which contains:

(i) The warning: "Sunlamp—DANGER—Ultraviolet radiation. Follow instructions."

(ii) The UV lamp equivalency code as defined in Annex CC of IEC 60335-2-27, Ed. 5.0, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (i) of this section. In determining the "UV code" component of the UV lamp equivalency code, output must be measured in accordance with IEC 61228, Ed. 2.0 (iii) The model identification, if applicable.

(iv) The words "Use ONLY in fixture equipped with a timer."

(3) *Label specifications.* (i) The labels prescribed in paragraph (d)(1) of this section for sunlamp products shall be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed immediately before the use of the product. The labels shall be of sufficient durability to remain legible throughout the expected lifetime of the product. To be legible and readily accessible to view, the sunlamp product warning statement required by paragraph (d)(1)(i) of this section shall comply with the following:

(A) It shall appear on a prominent part or panel displayed under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed when the person who will be exposed approaches the equipment;

(B) It shall be physically separate and visually distinct from the other required label information;

(C) It shall meet the following font size and font color requirements: The lettering in the word "DANGER" shall be at least 10 millimeters (height), at least double the height of the other words in the warning statement, in all capital letters, and in red or another font color that is legible and distinct from the other words in the warning statement. The lettering in the other words in the warning statement shall be at least 5 millimeters (height) and in lower case or title case.

(ii) The information prescribed in paragraph (d)(2) of this section for ultraviolet lamps shall be permanently affixed or inscribed on the lamp itself so as to be legible and readily accessible to view, as well as on the packaging of the lamp.

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such information or alternate wording for such label, as appropriate.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by §§ 1010.2(b) and 1010.3(a) of this chapter, the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular, e.g., if they do not diminish the impact of the required statements, and are not prohibited by this chapter.

(e) *Informational requirements—User information.* Each manufacturer of a sunlamp product or ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to minimize the potential for injury to the user, including the following information:

(1) *Sunlamp Products.* The users' instructions for a sunlamp product shall contain:

(i) A reproduction of all the label information required by paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the sunlamp product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the sunlamp product including the function, use, and setting of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the sunlamp product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, which will, when installed and used as instructed, result in continued compliance with the standard.

(v) Manufacturers of sunlamp products shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each sunlamp product: Adequate instructions for assembly, operation, and maintenance, including clear warnings concerning precautions to avoid possible exposure to ultraviolet radiation during assembly, testing, and maintenance, and a schedule of maintenance necessary to keep the sunlamp product in compliance with this section.

(2) *Ultraviolet lamps.* The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction of the label information required in paragraph (d)(2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the sunlamp product must always be followed to avoid or to minimize potential injury.

(3) *Promotional materials.* Manufacturers of sunlamp products shall provide or cause to be provided in all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale, a legible reproduction (color optional) of the warning statement required by paragraph (d)(1)(i) of this section.

(f) *Test for determination of compliance.* Tests on which certification under § 1010.2 of this chapter is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the sunlamp product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument. The performance requirements for the measuring instrument specified in IEC 60335-2-27, Ed. 5.0 Clause 32.101, which is incorporated by reference, shall apply.

(g) *Modification of certified sunlamp products.* The modification of a sunlamp product, previously certified under § 1010.2 of this chapter, constitutes manufacturing under the Federal Food, Drug, and Cosmetic Act if the modification affects any aspect of the product's performance or intended function(s) for which this section has an applicable requirement. The person who performs such modification shall recertify and re-identify the sunlamp product in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

(h) *Medical device classification regulation.* Sunlamp products and ultraviolet lamps intended for use in sunlamp products are subject to special controls and restrictions on sale, distribution, and use as set forth in § 878.4635 of this chapter.

(i) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the following sources. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(1) American National Standards Institute (ANSI), 1889 L St. NW., 11th Floor, Washington, DC 20036, [storemanager@ansi.org](mailto:storemanager@ansi.org).

[www.ansi.org](http://www.ansi.org), 202-293-8020.

(i) ANSI C81.10-1976, "Specifications for Electric Lamp Bases and Holders—Screw-Shell Types," dated September 1976.

(ii) [Reserved]

(2) International Electrotechnical Commission (IEC), EC Central Office, 3 rue de Varembe, CH-1211 Geneva 20, Switzerland, [www.iec.ch](http://www.iec.ch), call 41-22-919-02-11.

(i) IEC 60335-2-27, Ed. 5.0: 2009-12, "Household and Similar Electrical Appliances—Safety—Part 2-27: Particular Requirements for Appliances for Skin Exposure to Ultraviolet and Infrared Radiation," dated December 2009.

(ii) IEC 61228, Ed. 2.0, "Fluorescent Ultraviolet Lamps Used for Tanning—Measurement and Specification Method," dated January 2008.

Dated: December 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-32023 Filed 12-18-15; 8:45 am]

BILLING CODE 4164-01-P



## 2016 Meeting Schedule

Date	Location
<p><b>January 22, 2016</b> 9:30 – 11:30</p>	<p><b>Anne Arundel Medical Center Belcher Pavilion – 7<sup>th</sup> Floor Classroom “5”</b> 2000 Medical Parkway Annapolis, MD 21401</p>
<p><b>May 13, 2016</b> 9:30 – 11:30</p>	<p><b>Anne Arundel Medical Center Belcher Pavilion – 7<sup>th</sup> Floor Classroom “5”</b> 2000 Medical Parkway Annapolis, MD 21401</p>
<p><b>September 23, 2016</b> 9:30 – 11:30</p>	<p><b>Anne Arundel Medical Center Belcher Pavilion – 7<sup>th</sup> Floor Classroom “5”</b> 2000 Medical Parkway Annapolis, MD 21401</p>
<p><b>Annual Conference November 15, 2016</b> <i>(all day conference)</i></p>	<p><b>23<sup>rd</sup> Annual Maryland State Council on Cancer Control Cancer Conference</b> Anne Arundel Medical Center Belcher Pavilion- 7<sup>th</sup> Floor</p>