DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Sunlamp Products; Proposed Amendment to Performance Standard

Docket No. FDA-1998-N-0880 (Formerly 1998N-1170)

Preliminary Regulatory Impact Analysis
Initial Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

Economics Staff
Office of Planning
Office of Policy, Planning, and Legislation
Office of the Commissioner

DECEMBER 2015

Submit either electronic or written comments on the proposed regulatory impact analysis by March 21, 2016.

Instructions: All submissions received must include the Agency name and Docket No. FDA-1998-N-0880 (Formerly 1998N-1170) and RIN 0910-AG30 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Submit written comments in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Analysis of Impacts

We have 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 (Public Law 104-4). Executive Orders 12866 and 13563 direct us 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. We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities would incur costs less than 0.5 percent of average annual shipments, we have determined that the proposed rule would not have a significant economic impact on a substantial number of small entities, but the impacts are uncertain so we explicitly seek comment on this impact.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires us to 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. This proposed rule would not result in an expenditure in any year that meets or exceeds 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 ultraviolet (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

A. Need for Federal Regulatory Action

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. Advances in scientific knowledge and changes in the use of these products warrant an update to the regulations, last updated in 1985. Existing standards are based on an outdated

understanding of photobiological science and were developed when indoor tanning, now a billion dollar industry, was in its infancy. Also since the 1985 update, there has been a surge in the incidence of skin cancers and a series of studies showing many sunlamp product users are not following FDA recommendations and are overexposed to UV radiation. This proposed rule seeks to facilitate compliance, improve awareness among operators and consumers about risks of use, and ultimately improve public health.

The market failure we address with this proposed rulemaking is one of inadequate information. Prospective sunlamp product owners need to understand the risks of use to inform their purchase decisions; sunlamp product users need to understand the risks of use and are aided by clear user instructions that minimize negative health impacts associated with use. Recent developments in photobiological science are not easily understood by the general public and typical consumers are unlikely to possess this information. We do not expect sunlamp product manufacturers to keep abreast of the current state of photobiological science and if they did, we could not count on them voluntarily providing it to consumers if there were a perceived potential financial disincentive for doing so.

Market failure from a lack of information does not necessarily need to be addressed by government intervention. In markets where consequences of buyer or user errors are minor, consumers can test goods through trial and error. Consumers can also work collectively to gather product information or pay to obtain information from knowledgeable third parties. These approaches do not always work. When consumer errors are costly or when reliable product expertise is costly to find, obtaining product information through trial and error or from third party sources may not be practical.

The lack of accessible information about sunlamp product standards and the consequences of misuse of sunlamp products support intervention. Meaningful performance and informational standards for sunlamp products provide purchasers and consumers with information needed for informed buying and safe use that they would otherwise be unable to find.

Despite the obvious public health benefits from standards for sunlamp products, we cannot count on manufacturers voluntarily adopting them. Manufacturers would face the full cost of meeting these standards, while the benefits of these standards would be broadly distributed among the millions of users. Private returns alone gained from adopting these standards would not be adequate to ensure compliance, even if social benefits greatly exceeded the cost of compliance. We cannot necessarily expect sunlamp product manufacturers to voluntarily adopt standards based on the most recent scientific developments, particularly if consumers are not in a position to demand it. Left to their own profit-maximizing decisions and facing consumers without the ability to demand updated science-based standards, at least some manufacturers would choose to make products that did not meet such standards. Public action of some kind is required to align performance standards with science and to ultimately improve public health.

The appropriate approach to updating sunlamp product standards is notice and comment rulemaking at the Federal level. FDA has regulated sunlamp products since 1979 and has published performance standards for these devices in § 1040.20. As regulations, performance standards have recognized official standing and we convey that they are not likely to change in the near future, reducing regulatory uncertainty and facilitating compliance and enforcement.

Moreover, failing to revise our current regulations would prevent manufacturers from voluntarily adopting standards consistent with current science and in the interest of public health.

B. Background

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. There are also smaller "tabletop" products that are often marketed to home users. UV radiation-emitting products not used for indoor 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 analysis.

The Agency contracted with the Eastern Research Group, Inc. (ERG) to estimate the economic impact of updating sunlamp product performance standards. ERG's report, "Cost Analysis of Performance Standards" (ERG Report) is summarized here and is on file with the Division of Dockets Management (Ref. 1).

FDA originally developed performance standards for sunlamp products in 1979. The standard was revised in 1985 to bring the timer requirement in line with current technology at the time (Ref. 2). The revised performance standard remains in effect. Since the issuance of the revised performance standard, there have been additional changes in product technology, in the use of sunlamp products, in our knowledge regarding the public health risks from exposure to UV radiation, and in our knowledge regarding the effective communication of risk information to sunlamp product users.

The business of indoor tanning, immature in 1985, has grown to be a $2.7 billion industry in the United States (Ref. 1). According to the ERG Report, most indoor tanning is taking place

at one of the 18,000 to 19,000 professional indoor tanning facilities. Such establishments typically have 10 or more bed or booth tanning units. There are also 15,000 to 20,000 health clubs, spas, and other commercial establishments that offer tanning services in addition to their primary source of revenue. These establishments may have one or two tanning units. According to the Indoor Tanning Association, 30 million Americans visit tanning facilities each year; however, the 2010 National Health Interview Survey (NHIS) and the 2011 Youth Risk Behavior Survey (YRBS) found about 14.5 million users between the ages of 15 to 64 with an average of 19.6 visits per year (Ref. 3).

We do not know of a published estimate of the number of sunlamp products in use. Assuming an average of 12 units in each of 18,500 existing tanning facilities and 2 units in approximately 17,500 health clubs and other commercial establishments offering tanning services, there are about 257,000 units in commercial establishments.

There are little publicly available data on the size of the home tanning market. ERG obtained estimates that the home market was 7.5 percent, 10 percent, 33 percent, or perhaps more than half of the market for tanning beds (Ref. 1). The individual estimates ERG obtained from manufacturers and distributors vary because of the lack of published estimates and because each entity observes its own market share of home units. For the purposes of this analysis, we assume that about 10 percent of sunlamp products are used in the home or about 29,000 of 286,000 total units (257,000 x 1/9 = 29,000). This home market assumption is not part of our quantified cost estimates, but the existence of a home market emphasizes the importance of elements of this proposed rule addressing home users. We request comment on the size of the home market for sunlamp products.

The ERG Report identifies five U.S.-based sunlamp product manufacturers (but allows for as many as eight) and a single U.S.-based manufacturer of UV lamps (Ref. 1). We do not know of a published estimate of unit sales. A tanning booth or bed can last 10-20 years, implying between 5 and 10 percent of units are replaced each year. Assuming 9 percent of units are replaced each year, annual industry unit output for the 5 manufacturers would be about 26,000 units, or an average of 5,200 for each of 5 manufacturers. This estimate could overstate actual output if the indoor tanning industry is shrinking and used equipment is satisfying some of the demand for new units. If home users are responsible for 10 percent of the new unit purchases, about 2,600 new units are sold to home users annually. The home market share of new units could be smaller if home users are purchasing used equipment.

The ERG Report (Ref. 1) identifies 10 U.S.-based sources of protective eyewear for the U.S. market but does not specify whether these sources are U.S. manufacturers or are U.S. firms distributing product manufactured outside the United States. We do not know the size of the market for eyewear for use with sunlamp products or fraction of the market imported from outside the United States and invite comment.

Sunlamp products emit UV radiation to induce tanning. The adverse effects of UV radiation are well known (Refs. 4 and 5). 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, but quantifying a causal relationship is difficult. 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, and other factors. Nevertheless, a recent meta-analysis by Boniol et al. found a 1.8 percent (95

percent confidence interval 0 percent to 3.8 percent) increase in the risk of melanoma for each additional session of sunbed use per year (Ref. 6).

The projected numbers of new melanomas and deaths from melanoma in 2014 are 76,100 and 9,710 (Ref. 7). The two most common forms of skin cancer are basal cell carcinoma and squamous cell carcinoma, usually combined in cancer statistics and referred to as non-melanoma skin cancer (NMSC). The incidence of these cancers is somewhat uncertain, as they are not reported to major cancer tracking registries, such as the National Cancer Institute Surveillance Epidemiology and End Results (SEER) database. The estimated number of new NMCS treated in 2013 is 2.2 million with about 3,170 deaths (Ref 8).

We could not find a suitable direct measure of society's willingness to pay to avoid a case of melanoma or NMSC in a search of the literature. To value the willingness to pay to avoid a fatal case we therefore used the value of a statistical life (VSL) approach. A VSL is a summary measure for the dollar value of small changes in mortality risk experienced by a large number of people. For fatal cases we used the Environmental Protection Agency recommended VSL of $7.9 million ($8.2 million in 2012 dollars) to value reduced mortality (Ref. 9 at p. 7-11). To derive the values for nonfatal cases we used a variety of sources to estimate treatment costs weighted by level of treatment, and estimates for other human health-related costs, including intangible costs.

Societal cost to treat NMSC. For an estimate of the medical cost to treat a case of NMSC we used data from a study by Chen et al. (Ref. 10) where the authors estimated the cost of treatments by office setting. The authors estimated an average treatment cost for NMSC, weighted by setting (where the procedures was performed), of $588 per episode of care. In order to capture the indirect and intangible costs per episode we used data from a study by the Lewin

Group, Inc. (Ref. 11) on the burden of skin disease. Assuming that the relationship between the estimates of the total burden of NMSC primary and intangible costs would be the same on an average per case basis, we calculated the ratios between the totals of treatment costs to other costs reported in the Lewin study. We then applied these factors to our estimate of per case direct medical treatment costs. The cost estimates in the Lewin study included a measure of lost future earnings. Because we are using a VSL approach, which incorporates this value, we needed to remove lost future earnings from Lewin's cost variable before calculating our ratios. The relevant data from the Lewin study and how we applied it to create our estimate of total social cost per case of NMSC are listed in Table 2. There is very little mortality risk due to NMSC. To determine the mortality-adjusted value, we used the ratio of annual deaths to new incidence (0.0014) and applied it to the VLS. The mortality-adjusted cost per case of NMSC was $12,729.

To the extent that issuance of this proposed rule would reduce the incidence of skin cancers, the benefits of the reduction would be delayed because of the latency periods between exposure and diagnosis. We do not know the latency periods precisely, but have obtained some information from published research. The latency period between first exposure to therapeutic ionizing radiation and the appearance of NMSC is estimated to be at least 20 years (Ref. 12). For this analysis, we assume a 20-year lag attributable to latency between issuance of a final regulation and any public health benefits. Discounting for 20 years at a 7 percent discount rate, the monetary value of an averted case of NMSC is $3,300.

Table 2: Calculation of social cost per case NMSC.

Measurement	Value	Line	Calculation	Notes
Annual direct costs (2005 $) Annual indirect costs less value of future earnings Annual intangible costs	$1,451 million $ 65.5 million $130.0 million	A B C		Lewin (Ref. 11) $48 million lost wages of patient and caregiver during treatment; $17.5 million lost wages patient during recovery
Ratio indirect to direct costs Ratio intangible costs and direct costs	0.045 0.090	D E	B/A C/A	Assuming the ratio of direct, indirect, and intangible costs for total burden of NMSC would be the same on a per case bases
Direct treatment costs (2001 $)	$586	F		Chen (Ref 10)
Direct treatment costs (2012 $)	$759	G		CPI for medical costs
Indirect treatment costs	$34	H	G x D	
Intangible costs	$68	I	G x E	
Total social cost to treat one case	$861	J	G+H+I	
Cost per mortality (VSL) (2012 $)	$8,237,311	K		EPA (Ref. 9) inflated to 2012 $ using GDP inflation adjustment factor (1.0427)
2013 Estimate new incidence 2013 Deaths Deaths to new incidence	2,200,000 3,170 0.0014	L M N	 M/L	ACS (Ref. 8)
Mortality cost per case	$11,869	O	K x N	
Total cost per case	$12,729	P	O+J	
Total cost per case discounted 20 years @ 7%	$3,289		P x 0.2584	Rounded: $3,300
Total cost per case discounted 20 years @ 3%	$7,048		P x 0.5537	Rounded: $7,000

Societal cost to treat melanoma. To estimate the direct cost to treat a new case of melanoma we used data on treatment costs by disease stage at diagnosis from a study by Tsao et al. (Ref. 13) and incidence rates by stage from SEER (see Table 3). We used the same method we used for estimating the cost to treat NMSC to estimate the indirect and intangible costs of

treating melanoma. The calculation of the social cost to treat melanoma is presented in Table 4. The mortality-adjusted value per episode is about $1.1 million. We used a 20-year latency period when calculating the benefit of an averted case because a study found that those who have received extensive UV therapy for psoriasis have a 5-fold increase for the rate of melanoma beginning 15 years after treatment and 10-fold increase after 25 years of follow-up (Ref. 12). With 20-year latency at a 7 percent discount rate, the societal cost of melanoma is $273,300 per episode.

Table 3: Calculation of the cost to treat a new incidence of melanoma (1997 $)

Stage of development	Share of new incidence**	Cost per case*	Weighted cost	
Stage I and unknown	65%	$1,350	$852	
Stage II	23%	$3,299	$759	
Stage III	8%	$41,670	$3,334	
Stage IV	4%	$42,410	$1,696	
Total weighted cost to treat new case of melanoma				$6,640
Cost to treat in situ melanoma***				$1,350

*Source: SEER years 2003-2009; ** Tsao (ref. 13); *** assumed equal to cost to treat Stage I

Table 4: Calculation of social cost per case of melanoma

Measure	Value	Line	Calculation	Notes
Annual direct costs (2005 $) Annual indirect costs less value of future earnings Annual intangible costs	$291 million $758 million $367 million	A B C		Lewin Group, Inc. (Ref. 11) Lewin estimate less estimated future earnings per mortality ($364,000)
Factor indirect to direct costs Factor intangible costs to direct costs	2.60 1.26	D E	B/A C/A	Assuming the ratio of direct, indirect, and intangible costs for total burden of NMSC would be the same on a per case basis
Direct Treatment costs melanoma (2012 $)	$9,498	H		Value calculated in table inflated using CPI medical goods 1997 to 2012
Indirect treatment costs	$24,790	I	H x D	
Intangible costs	$11,967	J	H x E	
Total treatment costs	$46,255	K	H+I+J	
Cost per mortality (VSL) (2012 $)	$8,237,311	L		EPA (Ref. 9) inflated to 2012 $ using GDP inflation adjustment factor (1.0427)
2013 Estimate new incidence 2013 Deaths Deaths to new incidence	76,790 9,480 12.3%	M N O	 N/M	ACS (Ref. 8)
Mortality cost per case	$1,016,925	P	L x O	
Total cost per case	$1,057,445	Q	K+P	
Total cost per case discounted 20 years @ 7%	$273,264		Q x 0.2584	Rounded to $273,300
Total cost per case discounted 20 years @ 3%	$585,492		Q x 0.5537	Rounded to $585,500

Reducing exposure to UV radiation would reduce the incidence of other skin diseases, including actinic keratoses (AK). AK are precancerous skin lesions, associated with exposure to UV radiation and are common in individuals over age 60. Left untreated, these lesions can progress to squamous cell carcinoma but most do not. They are typically treated through cryotherapy or surgical removal. An estimated 58 million people each year experience at least one AK. (Ref. 11 at p. 24).

Sunlamp product use has been associated with acute injuries such as skin burns and eye irritation. Multiple studies have found rates of injury indicating the device is not used safely. Data collected from the National Electronic Injury Surveillance System (Ref. 14) indicates that

during 2009-2010 there were an estimated 1800 hospital emergency room cases per year, resulting from the use of sunlamp products. It is likely that the actual number of injuries is higher because this estimate includes only cases that are initially treated in US hospital emergency departments. It does not include cases that are treated in outpatient clinics, physician's offices, or not medically treated at all (Ref. 14). We are aware of studies showing erythema rates after sunlamp product use from 18 to 55 percent (Ref. 15). One study of indoor tanning by adolescents found that 59 percent reported some skin injury from indoor tanning, half reported never receiving a warning about the health risks of indoor tanning, and more than half were not always told to wear goggles (Ref. 16). A cross-sectional study of more than 10,000 children and adolescents found that 25 percent of girls 15-18 used tanning beds and that 29 percent of girls expressed the opinion that it was worth getting a little burned to get a good tan (Ref. 17). One study found 95 percent of tanning facility patrons exceeded the times recommended by the FDA exposure schedules (Ref. 18). In general, the incidence of acute injuries like erythema are probably partly attributable to a lack of awareness or understanding among operators and users of the proper use of sunlamp products and of the risks of exposure to UV radiation.

We do not have a reliable estimate for the total number or rate of burn injuries from the use of sunlamp products, but previously cited studies indicate a substantial portion of the estimated 30 million sunlamp product users experience erythema after tanning. We are unaware of published cost estimates for acute injury from sunlamp product use, but costs from solar burns can be used as a proxy. Direct costs per case of sunburn have been estimated to be $3.12, primarily from the purchase of OTC medicines (Ref. 11 at p. 96).[1] Previously cited studies indicate many burns among sunlamp product users are fully anticipated or possibly desired, and

[1] Solar burns are associated with direct costs of $384 million and indirect costs of $1.2 million. Per case costs are obtained by dividing total costs by the estimated 123 million annual cases.

the use of willingness to pay measures for symptom relief from an intended injury may not be applicable.[2] Using estimated direct costs only, assuming millions of individuals are burned while using sunlamp products each year, an estimated annual cost from sunlamp product burns would be in the millions of dollars.

The current FDA performance requirement in § 1040.20 includes a limit on the proportion of UVC emitted, a timer system, including a maximum timer interval to limit the dose to the manufacturer's recommended exposure schedule, an emergency shutoff switch, eyewear that protects against UV radiation but permits the user to see clearly enough to read labels, and basic compatibility standards for lamps and sockets to prevent these UV lamps from being used in conventional lighting fixtures. Sunlamp product manufacturers are required to attach or affix a warning label to the exterior of the tanning bed or booth and include with the sunlamp product instructions for use and recommended exposure schedules. FDA has issued guidance documents regarding replacement lamp compatibility, the calculation of the maximum timer interval, and the establishment of exposure schedules.

This proposed rule, if finalized, would bring our regulations up to date with the last 25 years of photobiological science and our understanding of how these products are used. Standards have also evolved from advances in measurement science. FDA proposes to adopt certain internationally recognized standards in an effort to reduce the risks associated with tanning. In moving to these consensus standards, FDA would reduce the overall burden of compliance for firms that do business both in the United States and abroad. Our proposal would improve information provided to consumers to reduce exposure to UV radiation, e.g., by helping

[2] Geller (Ref. 17) finds 29 percent of surveyed girls believe getting burned to be part of getting a good tan. Individuals may be willing to pay some amount of money to be relieved of symptoms from burns they intended to get, but we cannot assume that tools designed to monetize the quality of life impact from disease or injury to be applicable.

consumers avoid exposure beyond what is necessary to achieve their desired result. We propose to change the performance standards regarding UVC irradiance, the sunlamp product timer system, exposure schedules and protective eyewear to align them with current knowledge and address known public health risks. We also propose to revise the label and informational requirements and to add codified language that would clarify that those who modify sunlamp product performance characteristics bear the responsibilities of manufacturers.

C. Benefits and Costs of the Proposed Rule

Our proposal would affect several aspects of the performance standards to reduce risks associated with use and improve public health. We describe the impacts of the parts of the proposal in terms of nine themes, estimate costs for each provision, and use ranges to capture uncertainty. The costs are summarized in Table 1 of this document. 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.

1. Performance Standards for Irradiation Ratio Limits

The proposed rule would replace the current limit on the ratio of UVB to UVC irradiance in current § 1040.20(c)(1) with an absolute limit on UVC irradiance. The cost in going from measuring a UVB to UVC irradiance ratio to measuring UVC irradiance would be too small to reliably quantify.

Sunlamp product manufacturers currently producing for European consumers are already likely to be familiar with IEC standards and would not face any additional burden from this change in irradiation limits. They may benefit from the proposed rule as they are currently complying with two sets of standards and would need to comply only with one. Moreover, this provision, as well as others that would adopt consensus standards, emphasizes the scientific basis for the standards, which could improve consumer observance of warnings and recommendations.

2. Performance Standards for the Timer System

The proposed rule would change the calculation of the length of time a sunlamp product would emit radiation without requiring someone to reset the timer. According to current § 1040.20(c)(2) and guidance, this maximum timer interval is defined to be 4 times the time required to obtain the minimum erythemal dose (MED) using the CIELYTLE action spectrum for erythema. The MED, as defined in the 1986 FDA Policy Letter, is the dose that causes Type II skin (skin that always burns and then tans slightly) to become slightly pink and was chosen to be 156 J/m^2. A timer should allow for a maximum dose of 624 J/m^2 before shutting off.

Different wavelengths of radiation have different capacities to burn. An erythemal action spectrum captures the relationship between wavelength and erythema. We propose to adopt the current consensus CIE Reference Action Spectrum for Erythema that has been repeatedly validated in the laboratory. Using the CIE action spectrum, the MED for Type II skin is

approximately 200 J/m^2. We also propose to revise our maximum timer interval to one that would result in an erythema-effective dose that would not exceed 500 J/m^2. Differences between the two action spectra vary according to wavelength, so there is no simple comparison between 624 J/m^2 using CIELYTLE and 500 J/m^2 using the consensus CIE Reference Action Spectrum. According to our own calculations, timer limits under the proposal would be 0.75 to 1.2 times the current timer limit. Timer limit differences would affect the radiation one would receive without resetting the sunlamp product timer during a tanning session, but impacts on total UV radiation exposure would be small relative to other factors such as the number of sessions and the length of each session. The provision would not meaningfully change the overall amount of radiation one would receive while tanning.

With or without issuance of this proposed rule, sunlamp product timers will continue to be calibrated as part of the manufacturing process to comply with the maximum interval. Other than changing the calculation approach, this change imposes no additional burdens on manufacturers. There may be a small one-time cost to adjust to making calculations using the new action spectrum, but such a cost would be too small to reliably quantify.

Our proposal to replace our current action spectrum with an international consensus action spectrum based on current science would bolster the perceived scientific validity of our sunlamp product performance standard. Many sunlamp product users fail to adhere to current recommendations when it would seem to be in their best interest to do so. The recommendations are based on photobiological science and are designed to help users obtain their desired outcome while minimizing exposure to UV radiation. Although we do not possess information on why users fail to adhere, failing to update our recommendations in 30 years undermines our message to sunlamp product users that our recommendations are based on current science. Updating our

recommendations to conform to consensus science-based standards not only makes our recommendations better but also bolsters the perceived validity of the recommendations and of the overall validity of the regulation of sunlamp products, which would be expected to improve adherence. Although we believe our use of consensus standards based on current science would be more likely to foster adherence, we have no way to quantify the potential benefit.

3. Protective Eyewear

Current § 1040.20(c)(4) requires that eyewear included with a sunlamp product allow through enough visible light to enable a wearer to be able to reset or turn off the timer. It also includes a maximum spectral transmittance limit for different regions of the UV spectrum. Proposed § 1002.1(b) would apply reporting requirements to manufacturers of protective eyewear that is intended to be used with sunlamp products.

We recognize most sunlamp product users are not sunlamp product owners and the eyewear they use is generally not the eyewear that was included with the sunlamp product at the time of purchase. We propose to revise the standard to apply to all eyewear intended for use with sunlamp products. In addition, we propose to quantify the current qualitative minimal transmittance requirement, mandating eyewear to have luminous transmittance of at least 1 percent. We also propose to adopt a new maximum 5 percent transmittance limit for visible light. Some new sunlamp products, not anticipated at the time of the last performance standard revision, include intense visible light sources. The proposed maximum transmittance limit would protect the eyes of users.

We view the proposed 1 percent minimum luminous transmittance as a measurable version of current requirements, so all eyewear in compliance with current regulations should comply with this provision. We assume currently marketed tanning eyewear to generally comply

with the luminous transmittance limit, but we are uncertain. Approximately 10 years ago, FDA tested eyewear sold with sunlamp products as part of the development of the IEC luminous transmittance limit we proposed to adopt. The tested eyewear generally complied with the 5 percent transmittance limit and would meet the requirements of this proposed rule. With the passage of time and the need for manufacturers marketing outside the United States to meet IEC standards, we would expect even greater compliance now. Moreover, our current Product Report Guide (Ref. 19 at p. 5) asks for the transmittance in the visible region. Based on the product reports we have reviewed, eyewear sold with sunlamp products generally complies with the proposed visible transmittance limit. The sunlamp product reports we receive indicate general compliance with the proposed luminous transmittance standard. We assume all or nearly all eyewear marketed for use with sunlamp products is currently tested by the manufacturer for spectral transmittance in the visible region and that this information would be used to calculate luminous transmittance for the purposes of compliance with the proposed requirement. We also assume that protective eyewear sold separately from sunlamp products is manufactured to the same specification as eyewear sold with sunlamp products. Explicitly including protective eyewear sold separately in this proposed rule should not increase costs to eyewear manufacturers. We do not know this with certainty and invite comment.

According to the ERG report, UV transmittance testing costs vary from as little as $100 per item to several thousand dollars. Multiple labs estimated a cost per product of between $100 and $200 (Ref. 1). ERG estimates as many as five companies provide eyewear in the United States, but notes that the products may actually be manufactured abroad. We do not know how much, if any eyewear currently sold in the United States is manufactured in the United States. Assuming a market with 5 U.S. manufacturers, each with 10 models, and 10 percent of currently

marketed model untested, there are 5 models that would need to be tested. If testing costs are $180 per model, additional testing could cost as much as $900 (Ref. 1).

If eyewear failed to comply with the proposed visible transmittance limit, we assume it would be removed from the market or would be modified to meet the proposed requirement, but we seek comment on this assumption. Based on the general compliance of currently marketed eyewear, the incremental cost of manufacturing eyewear to a visible light transmittance limit of 5 percent would be small relative to the cost of testing. If, as in the previous example, 5 of the 100 models of eyewear are not being tested and 2 of them require modification, they may need to be redesigned and retested. Assuming the properties of suitable lenses are known and that eyewear redesign takes 8 hours of managerial time at $112 per hour [3]plus an additional test at $180, the cost would be $1,076 per model or $2,152 for the assumed two models. Testing plus the previously calculated modification costs would be $3,052. Our past testing and review of recent product reports indicate manufacturers are generally meeting this proposed standard when they are not required to do so. For this reason, we assume the proposed rule would not increase manufacturing costs and we assume no ongoing annual costs, but we invite comment. Using the previous assumptions and annualizing over 10 years, the cost would be $406 at 7 percent and $345 at 3 percent. These estimates are uncertain and we welcome comment.

These costs of this provision, although uncertain, are justified by the provision's benefits. The proposed maximum transmittance limit would address risks from products that were not anticipated in 1985, reducing eye injuries from high intensity visible light sources. Potential damage from intense visible light, such as retinal lesions and blind spots, is often not

[3] Wage adapted from ERG report (Ref. 1, p. 2-1) management occupations SOC 11-0000, $55.92 increased 100 percent to account for overhead.

immediately apparent and may not be detected for years. Because of this lag between damage and detection, we do not know the current incidence of injury nor can we estimate the number of avoided injuries. Injury from unprotected exposure to intense visible light could be temporary discomfort or temporary impaired vision, but could also be permanent damage to sight. Failure to modify our performance standards for these newer products could result in situations where users believed their eyes are protected when they are not and would unnecessarily expose themselves to harm. We lack the information to perform even a rough breakeven analysis, but if even a small number of annual eye injuries are avoided over the millions of sunlamp product users, the benefits would exceed estimated annualized costs, which are estimated in the hundreds of dollars.

Proposed § 1002.1(b) would apply reporting requirements to manufacturers of protective eyewear. The Performance Standard for protective eyewear was last published in 1985 when most eyewear was sold with sunlamp products. The safety of eyewear was adequately assured through the regulation of the sunlamp products themselves. Now that most eyewear is sold separately from sunlamp products, FDA is requiring that the manufacturers submit Product and Supplemental Reports. As with the UV lamp requirements, these proposed provisions would provide assurance that testing and labeling were consistent with the performance requirements and that purchasers of problematic products could be identified. Our assumed five eyewear manufacturers would have, at most, three new models of eyewear each year. They would need to submit an Annual Report, plus for each model they would submit a Product Report or Supplemental Report. We assume a manufacturer with three new models would submit four reports per year. Based on our experience with reporting requirements, we estimate this process would take 30 minutes per report for a total of 2 hours per manufacturer or 10 hours for all

manufacturers. At a managerial labor rate of $112, the cost to eyewear manufacturers for the proposed reporting requirement would be $1,120 per year. Estimated annualized costs to eyewear manufacturers are $1,526 at 7 percent and $1,465 at 3 percent.

Our proposed minimum requirement for luminous transmittance would replace a qualitative standard that is impossible to measure with a quantifiable internationally recognized standard, which would facilitate compliance and make our standards easier to enforce.

4. UV Lamp Compatibility

Sunlamp product owners in need of a replacement lamp consult labeled compatibility lists. With the passage of time and changes in sunlamp product model names, the compatibility lists become outdated and the process for identifying replacement lamps is unnecessarily burdensome. Finding an appropriate lamp takes time, and difficulty in finding the right lamp could result in the use of an incompatible lamp, which could result in users exposed to unintentional levels of UV radiation. We propose to adopt standards that would simplify the identification of compatible replacement lamps. We would adopt existing international consensus standards for compatibility testing and labeling that are part of current IEC standards (Ref. 20).[4]

Proposed § 1040.20(d)(2)(ii) would require that UV lamp labeling include a replacement lamp equivalency code instead of a list of compatible replacement lamps. We assume UV lamp manufacturers would find it less burdensome to specify a replacement UV code in their label than an updated replacement list, but we do not quantify the benefit. Sunlamp product manufacturers would have to revise their device label to include the UV lamp equivalency code range to be used in the product. For sunlamp product manufacturers, we assume costs of

[4] UV lamp codes are in Annex CC of IEC 60335-2-27, Ed 5.0.

reformatting the label to be captured in section C.5 of this document. The labeled compatibility code would require less space than the currently required compatibility list, but we do not attempt to quantify the cost savings associated with this benefit.

According to the ERG report, the single U.S.-based lamp manufacturer does not use IEC UV codes and would have to test and label all of its models under the proposed rule. The manufacturer has an estimated 30 to 120 models and the cost of testing would be between $200 and $500 for each model. Under these assumptions, the cost of testing for the manufacturer would be between $6,000 and $60,000. A lamp manufacturer would purchase a replacement $50 ink stamp for each model. For 30 to 120 models, the ink stamp cost is $1,500 to $6,000. We have considered the possibility that some labels are etched onto lamps, but we do not know the costs or the extent to which it occurs and welcome comment on this issue. The cost to a manufacturer to test and label would be an estimated one-time $7,500 to $66,000. Annualized over 10 years, the range would be $1,000 to $8,800 at 7 percent and $850 to $7,500 at 3 percent.

Current § 1002.1 requires manufacturers of UV lamps to submit Product Reports. Proposed § 1002.1(b) would expand the set of reports covered and would extend the requirements to manufacturers of protective eyewear. Under this proposal, UV lamp manufacturers would be required to submit Supplemental reports, Annual reports, and to maintain test records and distribution records. These new, proposed requirements are made necessary by the new, proposed requirements for the testing and labeling of UV lamps. Requiring manufacturers to submit Product and Supplemental Reports to FDA and maintain Test Records helps to provide assurance that the testing and labeling are conducted in accordance with the new, proposed requirements. Requiring that UV lamp manufacturers maintain

distribution records allows for the notification of purchasers of products that are later identified as problematic.

Based on our experience with this industry, we estimate the sole U.S. manufacturer would submit eight supplemental reports each year in addition to a single Annual report. The annual report and supplemental report both require 2 hours of time, and manufacturers currently submit Product reports that would satisfy a requirement for supplemental reports. Thus, the proposed requirement for supplemental reports does not add to our cost estimate and we consider only the 2 additional hours for each annual report. The cost of 2 hours from a manager at $112 per hour is $224. We estimate recordkeeping would require 2 minutes each for test records and for distribution records for each of the manufacturer's 30 to 120 models, or 120 to 480 total minutes. The estimated cost of 120 to 480 minutes of managerial time at $112 per hour is $224 to $898. The estimated annual cost of annual reports and recordkeeping for the single U.S-based UV lamp manufacturer is $448 to $1,120.

Under this proposed rule, thousands of sunlamp product owners would no longer need to use often-outdated compatibility lists to find replacement lamps for their products. We expect the compatibility standards to save time and improve compliance. We do not have a reliable estimate of the benefit to sunlamp product owners, but if each of the estimated 286,000 beds needed one replacement lamp per year, if the proposed standardized system saved only 8 seconds per replacement, and if the time of the individual responsible for obtaining the replacement lamp was valued at only $21 per hour, the annual savings to sunlamp product owners (0.15 minutes x $0.35 per minute x 286,000 = $15,015) would exceed the high end of the annualized labeling and testing costs ($8,800). Home users would benefit, in particular, as they lack the expertise of a commercial establishment in identifying compatible lamps.

5. Revised Warning Label

We are aware of research, some of which we cited earlier in this document, finding that many sunlamp product users are not following published recommendations and may not be aware of product warnings. The failure to follow recommendations and heed warnings likely results in exposure to UV radiation beyond that necessary to attain desired results. We propose to revise the format of the required warning label based on FDA's research on communicating the risks of indoor tanning (Ref. 21). According to FDA's focus group research, the current warning label's format is not user-friendly and limits the effectiveness of its communication of the dangers associated with indoor tanning. Based on the findings from the study we propose to adopt the recommended bulleted format in revised § 1040.20(d).

Changing the warning label would result in one-time costs for manufacturers to redesign the label plus recurring costs from an increased label size. The ERG Report estimates a revision would require 2 to 4 hours of time from a graphic designer and 4 to 8 hours from a production manager. Assuming wages including benefits of $51 per hour for a graphic designer[5] and $112 per hour for a production manager, estimated labor costs to a manufacturer would be $550 to $1,100. The revision would require a printing plate charge of $60 to $70, and other charges of $25 to $75 (Ref. 1 at p. 2-1). ERG assumes manufacturers would receive adequate notice to exhaust existing label stock. Estimated one-time costs are $635 to $1,245 per manufacturer, or $3,175 to $9,960 for 5 to 8 manufacturers.

The revised warning language and bulleted format would result in a label about 40 percent larger than its current size (Ref. 1 at p. 2-2). ERG estimates that the larger label size

[5] Wage adapted from the ERG report (Ref. 1, p. 2-1) SOC 27-1024 graphic designer $25.46, increased 100 percent to account for overhead.

would increase per unit label costs from about $0.24 to $0.36. If each manufacturer produces 5,200 sunlamp product units per year, the 12-cent incremental annual cost associated with the larger label would cost $624 per year or $3,120 to $4,992 for an industry with 5 to 8 manufacturers. Combining one-time and annual costs and annualizing over 10 years, industry warning label costs would be $3,542 to $6,317 at 7 percent and $3,418 to $6,126 at 3 percent.

The revised label's improved ability to communicate risks of using sunlamp products would result in substantial public health benefit because an improved understanding of risks of use would reduce exposure to UV radiation by better enabling consumers to avoid exposure beyond that necessary to achieve desired effects. Assuming the number of indoor tanning consumers to be 14.5 million, and given the substantial percentages of users not following recommendations in the previously cited literature, millions of individuals are overexposed to UV radiation because they do not pay attention to the current warning label. Reducing exposure to UV radiation has the potential to reduce skin cancers including melanoma, actinic keratoses, burns, skin aging, and other health problems. Considering just a reduction in incidence of NMSC and using the estimated $3,300 per case when discounting at 7 percent, reducing UV exposure among the millions of consumers to avert two cases of NMSC each year (a reduction in overall NMSC incidence of 0.0001 percent) would exceed the high end of the range for estimated industry costs of $6,317.

6. Exposure Schedule

Human research conducted at FDA has found that individuals can tan with lower levels of UV radiation exposure than they would get following current recommendations (Ref. 22). Based on this research, proposed § 1020.40(d)(1)(iv) would require sunlamp product labels to

include an exposure schedule developed in accordance with the criteria in the IEC standard (Ref. 20).

ERG has estimated the one-time cost of formatting a revised exposure schedule for inclusion in the instructions (Ref. 1 at p. 4-1) and estimates the revised label would require 2 to 4 hours from a graphic designer and 2 to 4 hours of managerial time. At $51 per hour for the graphic designer and $112 for the manager, the labor costs per manufacturer would be $326to $652. Managerial time would include time spent learning the revised guidelines to establish an exposure schedule. For 5 to 8 manufacturers, the cost would be $1,630 to $5,216. Annualized costs would be $217 to $695 at 7 percent and $185 to $594 at 3 percent.

We do not know the extent to which individuals would adhere to an exposure schedule that complies with the proposed requirements. At any level of adherence, this proposal would reduce overall exposure to UV radiation, which would reduce skin cancers including melanoma, actinic keratoses, burns, skin aging, and other health problems. The benefit of eliminating one case annually of just NMSC, or 0.0001 percent of all cases of NMSC, using monetized benefits of an averted case of $3,300, would be several times greater than the high end of the range for annualized costs for this provision.

7. Additional Informational Requirements

Proposed § 1040.20(e)(3) would require manufacturers to include a copy of the warning label in all catalogs, specification sheets, and descriptive brochures, and consumer-directed Web pages on which sunlamp products are offered for sale. According to the ERG Report, manufacturers would be able to work the label into printed materials without the need to print additional pages (Ref. 1 at p. 3-1). Manufacturers would have to develop versions of warning labels for the many types of printed materials they distribute. Label development would require

an estimated 4 to 20 hours from a graphic designer at $51 per hour and 4 to 20 hours from a manager at $112 per hour (Ref. 1 at p. 3-1). Under these assumptions, labor costs would be $652 to $3,260 including $204 to $1,020 for graphic design and $448 to $2,240 for management. Industry labor cost for 5 to 8 manufacturers would be $3,260 to $26,080. Annualized over 10 years, the costs would be $434 to $3,470 at 7 percent and $371 to $2,968 at 3 percent.

Proposed § 1040.20(e)(1)(v) would require that manufacturers provide assembly, maintenance, and operation instructions. We do not know the incidence of injury among those assembling, maintaining, or testing sunlamp products, but the required information protects operators from inadvertent exposure to UV radiation. These instructions would be particularly important to home users who are less experienced at maintaining sunlamp products and might otherwise be subject to accidental UV exposure.

8. Modification of Certified Products

Proposed § 1040.20(g) would codify FDA's longstanding position that those who change the function or performance characteristics of a sunlamp product are manufacturers and would need to recertify and re-identify the device. Some sunlamp product owners are unaware of FDA's position and view product modifications as a less expensive alternative to purchasing a new sunlamp product.

Our proposal in this part of the regulation would inform sunlamp product owners of the consequences of their potential actions. Some owners, otherwise inclined to alter their sunlamp product's performance characteristics, would likely be deterred from doing so by the required information. An owner may purchase a new sunlamp product instead of making modifications, but such costs would be incurred to comply with an existing requirement and the incremental

costs of this proposed rule would be less than the public health benefit from preserving the integrity of the performance standards and improving user safety.

9. Copy of IEC Standards

Our incorporation by reference of IEC standards would require some sunlamp product and UV lamp manufacturers to purchase an official copy. A paper copy of the referenced IEC standard, IEC 60335-2-27, Ed. 5.0, costs 190 Swiss francs.[6] At 1.10183 U.S. dollars per Swiss franc, the cost would be approximately $210.[7] Assuming the 5 to 8 sunlamp product manufacturers, the single U.S.-based UV lamp manufacturer, and 5 eyewear manufacturers would need to purchase a copy, the one-time cost to the 11 to 14 manufacturers would be $2,303 to $2,931. Annualized over 10 years, the cost would be $334 to $390 at 7 percent and $262 to $306 at 3 percent.

Table 5.--Summary Of Estimated Costs

	One-Time Costs		Annual Costs	
	Low	High	Low	High
Irradiation Ratio Limits	too small to quantify	too small to quantify	--	--
Timer System	--	--	--	--
Eyewear	$3,049	$3,049	$1,118	$1,118
Lamp Compatibility	$7,500	$66,000	$448	$1,120
Warning Label	$3,175	$9,960	$3,120	$4,992
Exposure Schedule	$1,630	$5,220	--	--
Additional Informational	$3,260	$26,080	--	--
Definition of Manufacturer	--	--	--	--

[6] Cost of a hard copy version of the document purchased from the IEC Web store: http://webstore.iec.ch/Webstore/webstore.nsf/Artnum_PK/43613.

[7] Rates obtained August 6, 2014 from http://www.xe.com/currencyconverter/convert/?Amount=1&From=CHF&To=USD.

IEC Standards	$2,303	$2,931	--	--
Total all Provisions	$20,917	$ 113,240	$4,686	$7,230
	Low	High		
Discounted Costs at 7 percent	$57,181	$151,390		
Discounted Costs at 3 percent	$61,498	$165,883		
Annualized at 7 percent	$8,141	$21,4498		
Annualized at 3 percent	$7,867	$19,447		

D. Small Business Analysis

The following analysis along with other sections of this document constitute the Agency's preliminary regulatory flexibility analysis as required under the Regulatory Flexibility Act.

This proposed rule would modify the performance standards for sunlamp products, UV lamps for use with sunlamp products, and eyewear for sunlamp product use. According to the Table of Small Business Size Standards, the U.S. Small Business Administration (SBA) considers institutional furniture manufacturing entities (North American Industry Classification System (NAICS) 337127) with 500 or fewer employees and electric lamp bulb and part manufacturers with 1,000 or fewer employees to be small (Ref. 23). We do not know the number of employees for each manufacturing entity, but all 5 to 8 sunlamp product manufacturers and the single UV lamp manufacturer would probably be classified as small under SBA size standards.

This proposed rule would not likely have a significant impact on a substantial number of small entities. A sunlamp product manufacturer would be affected by the proposed warning label format, revised exposure schedule, additional informational requirements, and the need to purchase a copy of the IEC standards. For a manufacturer, estimated one-time costs for these

provisions are $1,620 to $4,350 and annual costs are $625. Annualized over 10 years at 7 percent, total costs to the sunlamp product manufacturer are $840 to $1,200. The range of costs at 3 percent is $800 to $1,120. In Table 6 of this document, we express the annualized cost to sunlamp product manufacturers as a percentage of average establishment shipments, as reported by the Department of Commerce (Ref. 24 at Table 4). Using the high end of the range of estimated costs and using average shipments for manufacturers with one to four employees, estimated costs are 0.4 percent of shipments, well below the threshold considered significant (Ref. 25).

Manufacturers of UV lamps would be affected by the proposal to revise the lamp compatibility standards. Our cost estimate for this provision is a one-time $7,500 to $66,000 plus an annual $448to $1,120. Annualized over 10 years at 7 percent the costs are $2,118 to $9,230. The range of costs at 3 percent is $1,974 to $2,118. In Table 4 of this document, we express the annualized cost to sunlamp product manufacturers as a percentage of average establishment shipments (Ref. 26 at Table 4). Based on information from Dun and Bradstreet Company Lookup Report, we estimate annual sales at the affected manufacturer of UV lamps to be $12 million and estimated annualized costs to be 0.08 percent of shipments (Ref. 27). This is well below the range that has been cited as a threshold for significant impacts (Ref. 25).

This proposed rule also potentially imposes costs on manufacturers of protective eyewear. Our past testing and experience with submitted product reports indicate eyewear manufacturers already comply with the proposal, but we are not certain of this. We allow for the possibility that a manufacturer not in compliance would face initial testing costs of $900, $1,500 to redesign and retest noncompliant eyewear, and an annual $229 in reporting costs. Total annual shipments for the 72 ophthalmic goods manufacturers (NAICS 339115) with 5 to 9

employees, the smallest group with reported sales data, are $80.7 million (Ref. 28 at Table 4). A one-time cost of $2,400 and annual costs of $229 would result in annualized costs of $548. This would be 0.05 percent of average shipments of $1.1 million and would fall below cited thresholds for significant impacts.

Table 6.--Small Entity Characteristics and the Impact of the Proposed Rule

	Institutional Furniture Manufacturing (NAICS 337127)	
No. of Employees	<5	<10
Total Value of Shipments ($1000)	65,466	145,020
No. of Establishments	235	319
Average Value of Shipments ($)	278,579	454,608
High Estimate of Annualized Costs as a Percentage of the Average Value of Shipments	0.43%	0.26%
Low Estimate of Annualized Costs as a Percentage of the Average Value of Shipments	0.30%	0.18%

Table 7.--Small Entity Characteristics and the Impact of the Proposed Rule

	Electric Lamp Bulb and Part Manufacturing (NAICS 335110)	
No. of Employees	<5	Company
Total Value of Shipments ($1000)	4,998	12,000
No. of Establishments	16	1
Average Value of Shipments ($)	312,375	12,000,000
High Estimate of Annualized Costs as a Percentage of the Average Value of Shipments	2.95%	0.08%
Low Estimate of Annualized Costs as a Percentage of the Average Value of Shipments	0.68%	0.02%

Table 8.--Small Entity Characteristics and the Impact of the Proposed Rule

	Ophthalmic Goods Manufacturing (NAICS 339115)	
No. of Employees	5-9	10-19
Total Value of Shipments ($1000)	80,718	136,222
No. of Establishments	72	69
Average Value of Shipments ($)	1,121,083	1,974,232

High Estimate of Annualized Costs as a Percentage of the Average Value of Shipments	0.05%	0.03%

We find that this proposed rule would not have a significant impact on a substantial number of small entities, but the impact is uncertain and we invite comment.

E. References

1. Eastern Research Group (ERG) (2011). "Cost Analysis of Sunlamp Performance Standards," submitted to FDA, August 8, 2011.

2. Department of Health and Human Services, FDA, 21 CFR Part 1040 (Docket No. 82N-0188), "Sunlamp Products; Performance Standard," 50 FR 36548, Friday, September 6, 1985.

3. Centers for Disease Control and Prevention. "Use of Indoor Tanning Devices by Adults – United States, 2010". MMWR 2010, Vol. 61, No. 8.

4. IARC Working Group on Artificial Ultraviolet Light (UV) and Skin Cancer: The Association of Use of Sunbeds with Cutaneous Malignant Melanoma and Other Skin Cancers: A Systematic Review. International Journal of Cancer 120:1116-1122.

5. Gallagher R. P., Spinelli, J. J., and Lee, T. K.: Tanning Beds, Sunlamps, and Risk of Cutaneous Malignant Melanoma. Cancer Epidemiology, Biomarkers and Prevention 2005; 14: 562-566.

6. Boniol, M. et al., "Cutaneous Melanoma Attributable to Sunbed Use: Systematic Review and Meta-Analysis", British Medical Journal, 345:e4757, July 2012.

7. American Cancer Society (ACS) (2013). Cancer Facts and Figures 2013. American Cancer Society; 2014.

8. American Cancer Society (ACS) (2013). Cancer Facts and Figures 2013. American Cancer Society; 2013.

9. U.S. Environmental Protection Agency, "Guidelines for Preparing Economic Analyses," National Center for Environmental Economics, December 2010, http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html.

10. Chen, JG et al., "Cost of non-Melanoma Skin Cancer Treatment in the United States", Dermatol Surg 2001:27:1035-38.

11. The Lewin Group, The Burden of Skin Diseases, 2005, The Society for Investigative Dermatology and The American Academy of Dermatology Association.

12. Psaty, E. L., et al., "Defining the Patient at High Risk for Melanoma," International Journal of Dermatology, 49, 362–376, 2010.

13.Tsao, H., et al., "An Estimate of the Annual Direct Cost of Treating Cutaneous Melanoma," Journal of the American Academy of Dermatology, 1998; 38(5 Pt. 1):669-80.14. National Electronic Injury Surveillance System--All Injury Program, operated by the US Consumer Product Safety Commission in collaboration with the National Center for Injury Prevention and Control, Centers for Disease Control, 2009-2010, http://www.cdc.gov/ncipc/wisqars.

15. Bouzari, N. and K. Nouri, "Indoor Tanning," Skin Cancer, chapter 60, pp. 672-678, Keyvan Nouri, Ed, McGraw-Hill.

16. Oliphant, J. A., et al., "The Use of Commercial Tanning Facilities by Suburban Minnesota Adolescents," American Journal of Public Health, 84:3, 476-478, 1994.

17. Geller A. C., et al., "Use of Sunscreen, Sunburning Rates, and Tanning Bed Use Among More Than 10,000 U.S. Children and Adolescents," Pediatrics, 109:6, 1009-1014, June 2002.

18. Hornung, R. L., et al, "Tanning Facility Use: Are We Exceeding Food and Drug Administration Limits?" Journal of the American Academy of Dermatology, 49:4, 655-661, October 2003.19. U.S. Department of Health and Human Services, "Guide for Preparing Product Reports for Sunlamps and Sunlamp Products (21 CFR 1002)," September 1995 (Address corrections August 2008), http://www.fda.gov/downloads/MedicalDevices/.../UCM119491.pdf.

20. 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.

21. 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.

22. Miller S. A., et al., "Dynamics of Pigmentation Induction by Repeated Ultraviolet Exposures: Dose, Dose Interval and Ultraviolet Spectrum Dependence," British Journal of Dermatology, 159:4, 921-30, 2008.

23. U.S. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," effective November 5, 2010, www.sba.gov/sites/default/files/Size_Standards_Table.pdf.

24. U.S. Department of Commerce Economics and Statistics Administration, "Institutional Furniture Manufacturing: 2002," EC02-31I-337127 (RV), issued December 2004, http://www.census.gov/prod/ec02/ec0231i337127.pdf.

25. U.S. Department of Health and Human Services, "Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services," May 2003, http://www.hhs.gov/execsec/smallbus.pdf.pdf.

26. U.S. Department of Commerce Economics and Statistics Administration, “Electric Lamp Bulb and Part Manufacturing: 2002,” EC02-31I-335110 (RV), Issued December 2004, http://www.census.gov/prod/ec02/ec0231i335110.pdf.

27. Dun and Bradstreet Lookup Report, 2009, search performed January 11, 2011.

28. U.S. Department of Commerce, Economics and Statistics Administration, “Ophthalmic Goods Manufacturing: 2002,” EC02-31I-339115 (RV), issued December 2004, http://www.census.gov/prod/ec02/ec0231i339115.pdf.