Restricted Sale, Distribution, and Use of Sunlamp Products

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SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

In the proposed rule entitled "General and Plastic Surgery Devices; Restricted Sale, Distribution, and Use of Sunlamp Products" (the Sunlamp Restriction proposed rule), FDA is establishing device restrictions for sunlamp products to address the risks to health that these devices pose to users. The potential reductions in the incidence of skin cancers and other illnesses or injuries resulting from this proposed rule are significant. Use of sunlamp products is a significant, independent risk factor in the development of skin cancers, including melanoma, the most concerning form of skin cancer. This proposed rule applies to sunlamp products (e.g., tanning beds and booths), which incorporate ultraviolet (UV) lamps intended for skin tanning; this proposed rule does not apply to other UV devices that are intended for therapeutic uses. This proposed rule establishes requirements on manufacturers of sunlamp products and on tanning facility operators at facilities where sunlamp products are offered for sale as the primary business (tanning salons) or nonprimary business (for example, a gym). FDA does not consider people who use their own sunlamp products (home users) to be "tanning facility operators."

The use of sunlamp products poses cumulative risks, so earlier use (i.e., beginning use at a young age) or more frequent use increases these risks. The scientific literature establishes that people who begin using sunlamp products at earlier ages, and people who use the devices more frequently are more likely to develop skin cancer (and/or other illnesses or injuries) compared to those who begin at older ages or use sunlamp products infrequently. However, even infrequent use of sunlamp products significantly increases the risk of illness or injury. Because the risks are cumulative, injuries or illnesses may not be apparent until years or decades after use.

In light of these risks, FDA has taken other initiatives related to sunlamp products. In 2014, we reclassified the devices from class I (general controls) to class II (special controls). Concurrently with the proposed rule, we also proposed to update the electronic product performance standard for sunlamp products.

Summary of the Major Provisions of the Proposed Rule

This restriction includes the following requirements for tanning facility operators:

1. Age restriction. Tanning facility operators must not permit use of sunlamp products unless the prospective user is age 18 or older;

2. Risk acknowledgment certification. Tanning facility operators must obtain each prospective user's signature on a prescribed risk acknowledgement certification before sunlamp product use and every 6 months after; and
3. User manual provision. Tanning facility operators must, 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.
4. Sunlamp product 510(k) holders 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.

Legal Authority

Sunlamp products (as that term is defined in FDA regulations) are both "devices" and "electronic products" under the Federal Food, Drug, and Cosmetic Act (FD&C Act). For devices, FDA is authorized 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 rulemaking proposes to establishes such restrictions under section 520(e) of the FD&C Act (21 U.S.C. 360j(e))).

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). Section 704(a) of the FD&C Act (21 U.S.C. 374(a)) authorizes FDA to inspect certain records relating to restricted devices.

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.

2. Purpose and Use of the Information Collection

FDA is proposing to establish device restrictions on sunlamp products to address the risks to health that these devices pose to users. The potential reductions in the incidence of skin cancers and other illnesses or injuries resulting from this restriction are significant.

The use of sunlamp products poses cumulative risks, so earlier use (i.e., beginning use at a young age) or more frequent use increases these risks. The scientific literature establishes that people who begin using sunlamp products at earlier ages, and people who use the devices more frequently are more likely to develop skin cancer (and/or other illnesses or injuries) compared to those who begin at older ages or use sunlamp products infrequently. However, even infrequent use of sunlamp products significantly increases

the risk of illness or injury. Because the risks are cumulative, injuries or illnesses may not be apparent until years or decades after use.

To address the risks to health that these devices pose to users, the proposed restriction includes requirements regarding age restriction, risk acknowledgment certification, and a user manual provision.

Respondents to the information collection are private sector, for-profit businesses.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 90% of the respondents will use electronic means to fulfill the information collection.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency responsible for the collection of information associated with sunlamp products. No similar information is currently collected by any other agency and, therefore, no similar information is available that can be used or modified for the purpose described.

5. Impact on Small Businesses or Other Small Entities

We estimate that 99% of the respondents are small businesses.

Based on our estimated impact on revenues, the rulemaking will have a significant impact on a substantial number of small entities. The revenue loss is generated by the same effect – reduced indoor tanning – that generates the public health gains. Moreover, the relationship between revenue loss and public health gain is direct. The direct relationship between the revenues of small businesses and the public health gains from the final rule greatly limits the options for regulatory relief. Exempting small businesses, for example, will virtually negate the rule. In addition, increasing the compliance period will delay the effects on both revenues and public health (see the Small Entity Analysis in the Regulatory Impact Analysis for the rulemaking).

FDA aids small businesses and manufacturers to comply with applicable statutes and regulations by providing guidance and information through the Division of International and Consumers Education (DICE) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DICE provides workshops, on-site evaluations and other technical and nonfinancial assistance to small businesses. The workshops make available publications and educational materials, which include medical device labeling information. The Division also maintains a toll-free 800 telephone number and a website which firms may use to obtain regulatory compliance information.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the information collection:

- Once, when the facility explains certification on user's first visit (878.4635(c)(1)),

- Biannually (semi-annually), when the facility maintains signed certification (878.4635(c)(1)),
- Occasionally, when the facility provides the user manual upon request (878.4635(c)(2)), and
- Occasionally, when the 510(k) holder provides, upon request, a copy of the sunlamp product user manual.

Under the rulemaking, the tanning facility operator must not permit the use of a sunlamp product unless it obtains each prospective user's signature on the risk acknowledgement certification prior to use of the sunlamp product, unless the prospective user has previously signed the risk acknowledgement certification within the preceding 6 months. The periodic re-certification will expose users to information about the risks and proper use of sunlamp products multiple times, which may help them understand and retain the information provided. As such, it may even help those who already have accurate information, for example, by reminding them about certain risks (such as the photosensitizing effects of medications) that may not have been relevant to them at the time they read and signed the previous certification. For users at the highest risk of developing skin cancer, particularly melanoma, re-certification may be especially beneficial if it prompts them more frequently than once a year to consult with a dermatologist or physician. As we stated in the preamble to the proposed rule, we do not believe that a 6-month interval is unduly burdensome, particularly in light of the known risks of the devices.

Section 878.4635(c)(2) of the proposed rule requires, 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. Our burden estimate assumes that each user will request a user manual once per year.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This is a new request for information collection approval.

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to respondents to this information collection.

10. Assurance of Confidentiality Provided to Respondents

Information that is made available in labeling is, by its nature, public information. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. All records and other information submitted to FDA are releasable under 21 CFR Part 20. FDA can and does routinely protect company proprietary information, but does not have on-site means of complying with the requirements for material classified in national security interests.

11. Justification for Sensitive Questions

The information collection does not include any questions that are of a sensitive nature, such as, sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Recordkeeping Burden

Activity/ 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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 2.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]	Total Capital Costs
One-Time Burden						
Facility explains certification on user's first visit (878.4635(c)(1))	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
Total one-time burden					85,836	2,027,800
Annual Burden						
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	

Table 2.--Estimated Annual Third-Party Disclosure Burden

Activity/ 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]	Total Capital Costs

[1] Total hours have been rounded to the nearest whole number.

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)).

12b. Annualized Cost Burden Estimate

The annual cost to respondents for submitting and maintaining information relating to the amendment of the sunlamp performance standard is $3,852,379 (rounded). The annual cost is based on the total burden hours (85,836 one-time hours + 128,304 annual hours = 214,140 total hours), multiplied by the average hourly wage for employees ($17.99). Wage is derived from the May 2015 Bureau of Labor Statistics Occupation Employment Statistics Survey (http://www.bls.gov/oes/current/oes_nat.htm), occupation code NAICS 812100 Personal Care Service, Occupation Code 39-9099.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Personal Care and Service Workers, all other	214,140	$17.99	$3,852,379

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

We estimate the one-time cost burden to explain new procedures will be $1,538,793 (rounded). The cost is based on the burden hours to explain the new procedures (85,536 hours) multiplied by the hourly wage for employees ($17.99). Wage is derived from the

May 2015 Bureau of Labor Statistics Occupation Employment Statistics Survey, occupation code NAICS 812100 Personal Care Service, Occupation Code 39-9099.

14. Annualized Cost to the Federal Government

    We estimate that reviewing the data associated with the certification records will require approximately two full-time equivalent employees (FTEs). The cost to the Federal government will be $566,974, based on a cost of $283,487 per FTE (which is the agency's projected average cost of an FTE including benefits*).

    *Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

    This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    Not applicable.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

    FDA is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

    There are no exceptions to the certification.