impact on a substantial number of small entities. Accordingly, an initial regulatory flexibility analysis is not required.

The proposed rule would not affect a substantial number of small entities.[16] Currently only 17 entities are registered with the FDIC as registered transfer agents. Additionally, the FDIC has not received any new registrations for several years. In fact, over the last 10 years, 18 entities have deregistered as transfer agents (the most recent deregistration was in 2014). Furthermore, if any currently registered transfer agent does not meet the threshold requirements, it could deregister if the proposed rule were adopted as a final rule. Therefore, the proposed rule would likely reduce burden on small entities by increasing the number of entities that could deregister with the FDIC. As such, the proposed rule would not have a significant economic impact on a substantial number of small entities.

C. Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the FDIC to use plain language in all proposed and final rules published after January 1, 2000. The FDIC invites comment on how to make this proposed rule easier to understand. For example:

- Has the FDIC organized the material to suit your needs? If not, how could the FDIC present the rule more clearly?
- Are the requirements in the rule clearly stated? If not, how could the rule be more clearly stated?
- Do the regulations contain technical language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes would achieve that?
- Is this section format adequate? If not, which of the sections should be changed and how?
- What other changes can the FDIC incorporate to make the regulation easier to understand?

List of Subjects in 12 CFR Part 341

Banks, banking, Reporting and recordkeeping requirements, Savings associations, Securities.

[16] In 2010, the OTS estimated that 5 savings associations would be required to register as transfer agents. 75 FR 22184 (2010).

Federal Deposit Insurance Corporation

12 CFR Chapter III

Authority and Issuance

For the reasons stated in the preamble, the Federal Deposit Insurance Corporation proposes to amend part 341 of chapter III of title 12, Code of Federal Regulations as follows:

PART 341—Registration of Securities Transfer Agents

■ 1. The authority citation for part 341 continues to read as follows:

Authority: Secs. 2, 3, 17, 17A and 23(a), Securities Exchange Act of 1934, as amended (15 U.S.C. 78b, 78c, 78q, 78q–1 and 78w(a)).

■ 2. Revise § 341.1 to read as follows:

§ 341.1 Scope.

This part is issued by the Federal Deposit Insurance Corporation (the FDIC) under sections 2, 3(a)(34)(B), 17, 17A and 23(a) of the Securities Exchange Act of 1934 (the Act), as amended (15 U.S.C. 78b, 78c(a)(34)(B), 78q, 78q–1 and 78w(a)) and applies to all insured State nonmember banks, insured State savings associations, or subsidiaries of such institutions, that act as transfer agents for securities registered under section 12 of the Act (15 U.S.C. 78*l*), or for securities exempt from registration under subsections (g)(2)(B) or (g)(2)(G) of section 12 (15 U.S.C. 78*l*(g)(2)(B) and (G)) (securities of investment companies, including mutual funds, and certain insurance companies). Such securities are qualifying securities for purposes of this part.

■ 3. Amend § 341.2 by revising paragraphs (h) and (i) to read as follows:

§ 341.2 Definitions.

* * * * *

(h) The term *covered institution* means an insured State nonmember bank, an insured State savings association, and any subsidiary of such institutions.

(i) The term *qualifying securities* means:

(1) Securities registered on a national securities exchange (15 U.S.C. 78*l*(b)); or

(2) Securities required to be registered under section 12(g)(1) of the Act (15 U.S.C. 78*l*(g)(1)), except for securities exempted from registration with the SEC by section 12(g)(2) (C, D, E, F, and H) of the Act.

■ 4. Amend § 341.3 by revising paragraph (a) and the last sentence in paragraph (c) to read as follows:

§ 341.3 Registration as securities transfer agent.

(a) *Requirement for registration.* Any covered institution that performs any of the functions of a transfer agent as described in § 341.2(a) with respect to qualifying securities shall register with the FDIC in the manner indicated in this section.

* * * * *

(c) * * * Form TA–1 may be completed electronically and is available from the FDIC at *www.fdic.gov* or the Federal Financial Institutions Examination Council at *www.ffiec.gov,* or upon request, from the Director, Division of Risk Management Supervision (RMS), FDIC, Washington, DC 20429.

■ 5. Amend § 341.5 by revising the last sentence in paragraph (b) to read as follows:

§ 341.5 Withdrawal from registration.

* * * * *

(b) * * * A Request for Deregistration form is available electronically from *www.fdic.gov* or by request from the Director, Division of Risk Management Supervision (RMS), FDIC, Washington, DC 20429.

* * * * *

§ 341.7 [Removed]

■ 6. Remove § 341.7.

By order of the Board of Directors.

Dated at Washington, DC, this 15th day of December, 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–31941 Filed 12–21–15; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2015–N–1765]

RIN 0910–AH14

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

AGENCY: Food and Drug Administration, HHS.

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 ''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.* 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.[1]

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

[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.

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 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.[2] 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

[2] See *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/ucm205684.htm.*

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

[$ millions]

	7% Discount rate, 5% impact	7% Discount rate, 1% impact	7% Discount rate, 10% impact	3% Discount rate, 5% impact	3% Discount rate, 1% impact	3% Discount rate, 10% impact
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

Note: The impacts are tied to the acknowledgement certification and changing habits, which we interpret as the effect of age restrictions in disrupting the development of a habit for indoor tanning.

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			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
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.[3] 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 [1]

Activity/21 CFR section	Number of recordkeepers	Number 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

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs
One-Time Burden						
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

[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).

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs
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	

[1] There are no operating and maintenance costs associated with this collection of information.

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

RISKS OF INDOOR UV TANNING

Food and Drug Administration (FDA) regulations require all users to certify that they have read the information below regarding both the dangers of exposure to ultraviolet (UV) radiation from indoor tanning devices and the proper use of these devices.

- UV radiation from indoor tanning devices can cause:
  - Skin cancer, including melanoma, the type of skin cancer responsible for the most deaths
  - Eye burns which can cause intense pain and negatively affect vision
  - Sunburn (discomfort, pain, tenderness on the skin)
  - Early skin aging, such as wrinkles and age spots

- You must not use this device if you are under 18 years of age.

- Do not use if you have skin that easily sunburns or does not tan, as you are unlikely to tan with these devices and you are at a higher risk for developing skin cancer.

- Do not use if you have any rashes or open wounds.

- Do not use beyond the manufacturer's recommended exposure schedule to avoid burns and over exposure. The manufacturer's recommended exposure schedule can be found on the device.

- Please consult your doctor or pharmacist about any medicines that you are taking before using indoor UV tanning devices. Certain medicines (for example, tetracycline) or skin products (for example, some cosmetics) can increase your sensitivity to UV radiation.

- Use appropriate protective eyewear. Failure to do so may result in short-term and long-term injury to the eyes such as severe burns, cataracts, or eye cancer. Unprotected exposure to the intense visible light from some indoor tanning devices can cause damage to your vision, which may be permanent.

- Consult your doctor if you or someone in your family has a history of skin cancer because UV tanning (whether indoors or outdoors) carries a higher risk for you.

- If you use indoor UV tanning devices and/or tan regularly outdoors, get regular skin cancer checkups from your doctor because you are more likely to develop skin cancer.

- Even if you follow these safety instructions, you are still at risk for skin cancer if you use indoor UV tanning devices.

- Report any injury, including burns, from the use of indoor UV tanning devices to FDA. You should make this report as soon as possible after the injury. Instructions for reporting are available at *https://www.accessdata.fda.gov/scripts/medwatch/* or call **1-800-FDA-1088.**

I, _____, am at least 18 years of age and have read, understood, and acknowledged the risks and proper use information stated above.

Signature and Date: _____

(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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1002 and 1040

[Docket No. FDA–1998–N–0880 (Formerly 1998N–1170)]

RIN 0910–AG30

Sunlamp Products; Proposed Amendment to Performance Standard

AGENCY: Food and Drug Administration, HHS.

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.* 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:

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