practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on charging for an investigational drug under an IND. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 collections of information in § 312.8 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default,* or *http://www.regulations.gov.*

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–11006 Filed 5–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2013–N–0461]

General and Plastic Surgery Devices: Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed Order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify ultraviolet (UV) lamps intended to tan the skin from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification, and to rename them sunlamp products. FDA is also designating special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information.

DATES: Submit either electronic or written comments on this proposed order by August 7, 2013. See section XI for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0461, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions 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.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0461. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or 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.

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—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (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) established 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). One type of general control provided by the FD&C Act is a restriction on the sale, distribution, or use of a device under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)). A restriction under section 520(e) must be implemented through rulemaking procedures, unlike the administrative order procedures that apply to this proposed reclassification under section 513(e) of the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. Applying these procedures, FDA has classified most preamendments device types (some remain unclassified).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified under section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process.

Those devices remain in class III and require premarket approval unless, and until, the device is classified or reclassified into class I or II under section 513(f)(2) or (3) of the FD&C Act or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

On July 9, 2012, Congress enacted FDASIA. Section 608(a) of FDASIA amended the device reclassification procedures under section 513(e) of the FD&C Act, changing the process from rulemaking to an administrative order. Prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. The proposed reclassification order must set forth the proposed reclassification and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of the FD&C Act.)

Section 513(e) provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, *e.g., Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (DC Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).) Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in 21 CFR 860.7(c)(2). (See, *e.g., Gen. Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Mfrs. Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA also 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. Sunlamp products are subject to the regulations for electronic product radiation control, including 21 CFR parts 1000 through 1010 and § 1040.20 (21 CFR 1040.20). The sunlamp products performance standard in § 1040.20 was originally published in the **Federal Register** on November 9, 1979 (44 FR 65352). In the **Federal Register** of September 6, 1985 (50 FR 36548), FDA amended § 1040.20 and made it applicable to all sunlamp products manufactured on or after September 8, 1986. FDA plans to propose amendments to this performance standard to reflect current scientific knowledge related to sunlamp 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 (Public Law 110–85).

II. Regulatory History of the Device

In a 1977 report, the General and Plastic Surgery Device Classification Panel and the Physical Medicine Device Classification Panel (the Panels) recommended that dermatologic UV lamps (devices that provide UV radiation intended primarily for the treatment of dermatologic disorders or for tanning) be classified into class II (see 47 FR 2810 at 2835; January 19, 1982).

The Panels recommended that dermatologic UV lamps be classified into class II because the Panels believed that the electrical and optical properties of the device must be controlled to prevent electrical shock, overexposure because of timer malfunction, and burns to eyes and skin. The Panels believed that general controls would not be sufficient to provide a reasonable assurance of safety and effectiveness, and that a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Physical Medicine Device Classification Panel also recommended that the device be sold only by prescription. The Panels identified the following risks to health for these devices:

1. Burns to skin and eyes: Improper shielding of eyes or overexposure of UV radiation to skin may result in burns. Also, excessive UV, visible, and infrared radiation from this device can be harmful to the eyes and skin.

2. Aging of skin: Excessive exposure to UV radiation may result in premature aging of skin.

3. Skin cancer: Excessive irradiation of the skin with UV lamps is correlated with increased incidence of skin cancer.

4. Photosensitivity: Exposure of patients with photosensitive skin to UV radiation may induce photosensitivity reactions.

FDA agreed with the Panels' recommendations and proposed that these devices be classified into class II in a proposed rule published in the **Federal Register** on January 19, 1982. However, in its final rule, published on June 24, 1988 (53 FR 23856 at 23868), FDA separated UV lamps for dermatological disorders and UV lamps for tanning. It classified the former in class II under 21 CFR 878.4630, but postponed classification of UV lamps for tanning in order to consider electrical safety information and to consider issuing a proposal to classify UV lamps for tanning in class I. FDA explained that the performance standard for sunlamp products at § 1040.20 addressed the risks to health presented by UV lamps for tanning other than electrical safety hazards. On November 15, 1988 (53 FR 46040), FDA proposed that 70 electromedical devices, including UV lamps for tanning, be classified in class I; FDA finalized this classification on November 20, 1990 (55 FR 48436 at 48440).

On December 7, 1994, FDA amended the classification when it published a final rule in the **Federal Register** (59 FR 63005) that exempted 148 class I devices from premarket notification (with limitations), including UV lamps for tanning. FDA determined that manufacturers' submissions of premarket notifications for UV lamps for tanning were not necessary for the protection of the public health at that time. Prior to the issuance of the 1994 final rule exempting UV lamps for tanning from premarket notification submission, some manufacturers of UV lamps for tanning had already submitted 510(k)s and received clearance for their devices, and at least one 510(k) for a sunlamp product has been cleared since then. As discussed further in this document, these devices may serve as

predicate devices for future 510(k)s if this order is finalized. On July 25, 2001, FDA made a technical amendment to the classification of UV lamps for tanning to state that the exemption from 510(k) is subject to the limitations in 21 CFR 878.9 (66 FR 38786 at 38803).

III. Device Description

The current device classification regulation for this product refers to it as an ''ultraviolet lamp for tanning,'' while the current electronic product performance standard for this product refers to it as a ''sunlamp product.'' Because both of these regulations describe the same product with the same intended use for tanning, FDA proposes to rename the device in this regulation for purposes of consistency and clarity. FDA proposes to identify this device as a ''sunlamp product'': An electronic product that includes one or more UV lamps and a fixture 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. This definition includes tanning beds, tanning booths, and UV lamps (bulbs) sold separately.

IV. Summary of Valid Scientific Evidence Concerning Reclassification

A. Public Health Benefit From Use of the Device

It is well recognized that sunlamp products are effective at producing a tan or darkening of the skin (except in very light skin individuals, who may burn instead of tan); and this is perceived by users as an aesthetic benefit. One study reported that 47 percent of college students had reported using a sunlamp product during the last year because it improved their appearance, despite 92 percent being aware of potential health risks (Ref. 1). Investigators have also looked at the effect of sunlamp products on mood to treat depression and/or seasonal affective disorder (SAD). The general therapeutic effect of visible light on SAD has been widely acknowledged (Ref. 2). However, there is no definitive evidence that UV radiation is effective in the treatment of SAD (Refs. 2 and 3).

Vitamin D has been the focus of recent research due to the possibility that it could help prevent some cancers and provide other health benefits (besides the well-recognized effect of contributing to bone health and preventing rickets). Some sunlamp products can produce Vitamin D (Ref. 4), but to date, it is unclear whether the benefit of such production outweighs the risks of use. A meta-analysis by Woo and Eide in 2010 (Refs. 5 and 6) supported the consensus medical and public health opinion that dietary supplements are safer than and as beneficial as tanning to produce Vitamin D. Furthermore, most people meet at least some of their Vitamin D needs through exposure to sunlight in moderate dosages. The World Health Organization (WHO) has stated that ''While sunbed use may increase vitamin D synthesis, * * * if people require more vitamin D than the sun can provide (for example, because of living in polar regions) this should be supplemented through diet rather than sunbed use'' (Ref. 7). A minority of researchers have argued that the potential benefit of sunlamp products might outweigh the health risks (Refs. 8 and 9).

Proponents of sunlamp products have also claimed that the use of sunlamp products may be helpful in promoting a base tan—a tan that prevents sunburns. However, a base tan, either from the sun or from sunlamp products, provides minimal protection against burning, and there is no evidence that a base tan provides any protection against premature aging of the skin or reduces the risk of skin cancer (cumulative UV exposure is likely to increase rather than decrease the risk of skin cancer) (Ref. 10).

B. Risks Posed by the Device

As stated previously, the original classification panels identified four risks to health associated with UV lamps. After considering the deliberations of the original reclassification panels mentioned in this document, the deliberations of a March 2010 General and Plastic Surgery Advisory Panel meeting on UV lamps for tanning, and published literature, FDA has determined that the risks to health listed in this document are associated with sunlamp products. The proposed special controls and forthcoming proposed amendments to the performance standard address these risks:

1. *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. 11 and 12). Skin cancers that have been associated with cumulative repeated UV radiation exposure include melanoma and non-melanoma skin cancers such as basal cell carcinoma and squamous cell carcinoma (Ref. 13). The risk may be higher in certain individuals with fairer, less pigmented skin, but can also be elevated in other individuals (Ref. 14). In addition to users with a personal history of melanoma having an increased risk of skin cancer, users with familial melanoma are also at increased risk for skin cancer—having one first-degree relative with melanoma doubles the risk of melanoma (Refs. 15 and 16). As with other radiation exposure, increased cumulative lifetime exposure results in increased skin cancer risk (for both melanoma and non-melanoma skin cancer) (Ref. 17).

There is increasing epidemiological evidence that tanning in childhood to early adult life increases the rate of melanoma (Refs. 18 and 19). Melanoma (of the two categories of skin cancer, this is the more concerning type due to greater potential for fatality) is currently the second leading type of cancer in young adults, and many experts believe that at least one cause for this is the increasing use of sunlamp products by this population (Ref. 20). FDA is also concerned that youths and adolescents may fail to appreciate the long-term dangers of sunlamp products (Refs. 21 and 22). The WHO has classified UV radiation from sunlamps as a class I carcinogen based on a 2009 International Agency for Research in Cancer (IARC) report that linked tanning bed use by individuals under age 35 to higher rates of melanoma and recommended that minors not use indoor tanning equipment (Ref. 23). This concern has led several states and one county in the United States, and several foreign governments, to ban the use of sunlamps by minors under a certain age (Refs. 24 and 25).

2. *Ocular Injury:* UV and visible radiation from this device can be harmful to the eyes if proper protective eyewear is not worn.[1] The intense light from sunlamps can cause keratitis and corneal burns, which can be painful and affect vision (Ref. 26). Artificial UV radiation has also been recently linked to ocular melanoma, which can cause vision loss and often spreads to other parts of the body (Ref. 27).

3. *Discomfort, Pain, and Tenderness on the Skin Resulting From Burns to the Skin due to Acute Overexposure to UV Radiation:* A recent evaluation showed that, despite protective measures instituted in commercial tanning facilities, 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. 28). Those findings are in line with a previous report that 58 percent of adolescent

[1] Ocular risks are addressed by labeling and performance requirements regarding eyewear at § 1040.20.

tanning bed users had experienced sunburns from exposure to sunlamps (Ref. 29). In certain individuals who are photosensitive, skin exposure to UV radiation may induce unexpected reactions such as rash, severe burns, and hypersensitivity reactions (Ref. 30). Sunlamps, like most light sources, also 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 light because those individuals lack the protective epidermal layer of the skin that provides the body's greatest protection from UV irradiation (Ref. 31).

4. *Skin Damage:* Cumulative, repeated exposure to UV radiation emitted by sunlamps may lead to accelerated aging of skin due in part to DNA and skin cell damage (Ref. 32). UV irradiation inhibits the production of collagen precursor molecules such as type I and type III procollagen (Ref. 33). UV irradiation stimulates skin metalloproteinases, which break down skin proteins that then lead to photoaging (Ref. 34). On a cellular level, UV radiation has been known to cause DNA damage through formation of thymidine cyclobutane dimers and via oxidative damage as a result of UV generated superoxide radicals (Ref. 11).

5. *Lack of Biocompatibility:* Device materials that are not biocompatible may, either directly or through the release of their material constituents, (i) Produce adverse local or systemic effects, (ii) be carcinogenic, or (iii) produce adverse reproductive and developmental effects. Although medical devices may have myriad biocompatibility issues (Ref. 35), the biocompatibility concerns from sunlamp products are likely limited to inflammatory skin reactions from contact with the materials from which the bed is made.

6. *Transmission of Infectious Diseases Due to Improper Cleaning and Disinfection:* This is a concern for any reusable device. Sunlamp products in an indoor tanning facility may be shared by dozens of users in a single day. Cleaning and disinfection practices, as well as training by facility operators, may vary from facility to facility. Because sunlamp product users directly contact the device with their skin, users with open wounds or lesions have the potential to transmit infectious diseases to subsequent users if the device is not properly disinfected between users.

7. *Electrical Shock:* Electrical shock hazards can pose a potential hazard to both operators and users. These are commonly caused by manufacturing defects or are the result of frequent use (*e.g.,* frayed wiring and broken connectors) (Ref. 36).

8. *Mechanical Injury:* Sunlamp products can pose a threat of blunt force injury or entrapment of a user due to the heavy and bulky nature of some of these devices and the fact that users are completely inside a tanning bed or booth during use. Such injuries and entrapment may result from manufacturing defects and may be exacerbated by frequent use.

9. *Use Error:* All of the risks discussed in this document may be exacerbated by human error. Human error can include misuse by the individual using the sunlamp to obtain a tan, including not wearing the correct eye protection, setting the exposure timer for longer than the recommended time in the exposure schedule for the individual's skin type or skin acclimatization, use by individuals who should not be exposed to the sunlamp, and not following the warnings and cautions. Use error also includes errors by the sunlamp product operator (for example, if used at an indoor tanning facility). These would include improper maintenance of fixtures leading to electrical shock or contaminated bed surfaces, improper maintenance or selection of lamps leading to overexposure, and incorrect use of timer according to recommended exposure schedule.

V. 2010 Classification Panel Meeting

On March 25, 2010, FDA held a General and Plastic Surgery Advisory Panel meeting on UV lamps for tanning (Ref. 37). The Panel reviewed and discussed recent information, including recent literature regarding the possible risks to the general public from intentional exposure to sunlamp products.

There is a growing body of literature showing an association of skin cancer with use of sunlamp products (Refs. 38 to 53), and the Panel discussed this information and other information related to the association of UV and skin cancer (both melanoma and non-melanoma) (Ref. 36). The Panel discussed whether changes to the current classification or current regulatory controls of UV-emitting devices (lamps) used for tanning are needed. The Panel generally agreed that stricter FDA regulation of these devices is necessary to control the serious risks they pose and unanimously agreed that the device should not be a class I device. No significant changes in risks relating to sunlamp products have been identified in the scientific literature since the 2010 panel meeting; the same risks identified prior to the 2010 panel meeting continue to be presented in literature.

The following summarizes some of the Panel members' responses to the questions posed and the Panel members' views related to a variety of measures that may be necessary to provide a reasonable assurance of safety and effectiveness:

- Regarding reclassification, there was general Panel consensus that UV lamps for tanning should not be class I devices. The Panel, however, appeared to be split on whether UV lamps for tanning should be reclassified into class III or class II in light of the risks they pose. Some Panel members believed that UV lamps for tanning should be reclassified into class III. Other Panel members recommended that UV lamps for tanning be classified as class II, and felt that special controls and/or restrictions related to, for example, age, skin type, and cancer risk, would mitigate the risks associated with the use of these devices and would provide a reasonable assurance of safety and effectiveness. A few Panel members discussed banning UV lamps for tanning. No Panel member recommended leaving these devices in class I.
- Regarding the user's age, some Panel members favored an age restriction for indoor tanning (*i.e.,* individuals under a certain age would not be permitted to use UV lamps for tanning), and agreed that the cutoff age should be 18.
- Some Panel members recommended that individuals with a genetic predisposition or family history of skin cancer should be subject to special restrictions (*e.g.,* education requirements) prior to using UV lamps for tanning because they were at a greater risk for developing skin cancer than the general population.
- Some Panel members recommended that users of UV lamps for tanning should have to read a form disclosing the risks related to UV lamps for tanning and acknowledge receipt of this information in writing prior to using the device. Panel discussion points for the disclosure of risk form related to topics such as genetic history, past history of melanoma, and usage in pregnancy. Some Panel members also supported more prominent posting of risks and warnings.

Docket No. FDA–2009–N–0606 was opened to receive comments on the regulation of sunlamp products (75 FR 1395; January 11, 2010). The majority of the input received via the open public docket supported strengthening FDA's regulation of these devices. Although many comments did not expressly

specify whether regulation of sunlamps should be strengthened or not, because most of these were related to the experiences of people with melanoma, FDA interpreted them to be in support of stricter regulation of sunlamps. Six comments of 139 total comments took the position that FDA should not change its current regulation of indoor tanning devices. Overall, the docket comments strongly paralleled the opinions of the Panel members.

VI. Proposed Reclassification

Based on the comments from the 2010 reclassification panel, the comments received in the docket, and FDA's assessment of new, valid scientific data related to the health benefits and risks associated with sunlamp products, FDA is proposing that sunlamp products be reclassified from class I (general controls) to class II (special controls) because general controls alone are insufficient to provide reasonable assurance of safety and effectiveness, and there is sufficient information to establish special controls to provide such assurance. FDA is not proposing to classify these devices in class III at this time because special controls can provide a reasonable assurance of safety and effectiveness.

The proposed special controls for this device—identified as follows (and underlined)—are necessary to provide a reasonable assurance of safety and effectiveness for this device. Failure to comply with the special controls that are included in a final order would cause a sunlamp product to fall outside this classification, and thus be classified in class III. Failure to obtain premarket approval of a class III device prior to marketing causes the device to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)).

(1) *Conduct performance testing that demonstrates the following:*

i. *Sunlamp products meet appropriate output performance specifications such as wavelengths, energy density, and lamp life; and*

ii. *Safety features, such as timers to limit UV exposure and alarms, function properly.*

Performance testing would have to demonstrate the appropriateness of sunlamp product output performance specifications, that the device performs within such specifications, and proper functioning of safety features such as timers and alarms. This requirement would mitigate the risks of skin cancer, discomfort, pain, and tenderness resulting from burns to the skin due to acute and/or cumulative overexposure to UV radiation, and skin damage by providing assurance that the output of the device is as expected and within appropriate parameters, and users are not unintentionally exposed to excessive radiation.

All performance testing and results must also be in conformance with the performance standard at § 1040.20.

(2) *Demonstrate that sunlamp products are mechanically safe to prevent user injury.*

Mechanical safety testing, such as cyclic fatigue testing and strength and materials testing, would help to ensure that the device's mechanical features can withstand multiple uses and are sufficiently durable so as not to injure users in the event of a failure of a mechanical feature.

(3) *Demonstrate software verification, validation, and hazard analysis.*

Appropriate software verification, validation, and hazard analysis would help to ensure that the software-controlled device functions (such as the timer, alarms, and basic functions like powering on and off) are in proper working order. This requirement would mitigate increased skin cancer risk from cumulative repeated UV radiation exposure, discomfort, pain, and tenderness resulting from burns to the skin due to acute overexposure to UV radiation, skin damage, and use error by helping to ensure a proper software/user interface and that proper instructions are provided to the operator in software outputs.

(4) *Demonstrate that sunlamp products are biocompatible.*

The biocompatibility of sunlamps would have to be demonstrated. Sunlamp products contact users' skin directly; therefore, a demonstration of biocompatibility would mitigate the risks of adverse local or systemic effects such as skin inflammation.

(5) *Demonstrate that sunlamp products are electrically safe and electromagnetically compatible in their intended use environment.*

The requirement to demonstrate electrical safety would mitigate the risks of electrical shock hazards for sunlamp product operators and users. The requirement to demonstrate electromagnetic compatibility would, in concert with other special controls, help ensure the mitigation of discomfort, pain, and tenderness resulting from burns to the skin due to acute overexposure to UV radiation by preventing electromagnetic interference with sunlamp hardware and software.

(6) *Labeling must bear all information required for the reasonable assurance of safe and effective use of the device. (Please see proposed 21 CFR 878.4635(b)(6)).*

These labeling requirements would help to discourage use of sunlamp products by those populations that are especially susceptible to the risk of skin cancer—persons under the age of 18 and persons with a prior personal history or family history of skin cancer. When combined with the labeling requirements of the sunlamp performance standard in § 1040.20, this labeling would help clearly communicate the risks of skin cancer to all users. A warning directing users of this device who are repeatedly exposed to sunlamp products to be regularly evaluated for skin cancer would help to clearly communicate the increased risk of skin cancer from cumulative UV radiation exposure and help to mitigate that increased risk. Clear communication of these risks and identification of susceptible populations would help potential users make an informed choice about use of sunlamp products and mitigate the increased risk of skin cancer from cumulative UV radiation exposure in all users by encouraging judicious use of these devices. This labeling would also help to mitigate other risks of use of sunlamp products, including discomfort, pain, and tenderness resulting from burns to the skin due to acute overexposure to UV radiation.

Transmission of infectious diseases due to improper cleaning and disinfection would be mitigated through the requirement to provide instructions for cleaning and disinfection of the device that have been validated for use with the sunlamp product they accompany, and a warning that the device not be used if skin lesions or open wounds are present. The contraindication against use if skin lesions or open wounds are present would also help to mitigate the risk of discomfort, pain, and tenderness resulting from burns to the skin due to acute overexposure to UV radiation by discouraging users who are particularly susceptible to this risk due to a lack of critical epidermal protection from using sunlamp products.

The requirement to provide labeling that contains all necessary information for safe and effective use of a sunlamp product would help mitigate use error as well as ocular injury by instructing users to wear protective UV eyewear at all times when using the device.

VII. Premarket Notification

Class II devices are subject to the 510(k) premarket notification requirement unless exempted under section 510(m) of the FD&C Act. Under this proposed reclassification, the Agency does not propose to exempt

these devices from premarket notification (510(k)) submission requirements as provided for under section 510(m) of the FD&C Act. The premarket notification requirement allows the Agency to review the technological characteristics, performance, intended use(s), and labeling of medical devices to ensure the devices are substantially equivalent to legally marketed predicate devices before they enter the market. Substantial equivalence requires that a new device must have (1) the same intended use as legally marketed predicates, and (2) either the same technological characteristics as a legally marketed predicate, or if there are significant differences, the differences must not raise new questions of safety and effectiveness and the performance data must demonstrate that the new device is at least as safe and effective as the legally marketed predicate device. (See section 513(i) of the FD&C Act.) This assures that new devices that differ significantly in terms of safety and effectiveness from devices already legally on the market will be subject to the more rigorous premarket approval requirement.

As discussed previously, FDA cleared several 510(k)s for sunlamp products prior to the issuance of the 1994 final rule exempting them from premarket notification submission. At least one 510(k) for a sunlamp product has been cleared since then under product code LEJ. These cleared sunlamp products can serve as predicates for substantial equivalence purposes.

VIII. Implementation Strategy

FDA is proposing the implementation strategy as follows regarding 510(k) submission and special controls compliance:

- Sunlamp product models that have not been marketed prior to the effective date of a final order based on this proposal, or have been marketed but are required to submit a new 510(k) under § 807.81(a)(3) because the device is about to be significantly changed or modified: [2] FDA would expect manufacturers of these devices to obtain 510(k) clearance and comply with all special controls before marketing the new or changed device.
- Sunlamp product models that have been marketed prior to the effective date of a final order based on this proposal: FDA would expect manufacturers to either submit a 510(k) and comply with all special controls within 1 year of the effective date of a final order, or cease marketing that model. During the 1 year following the effective date of the final order, FDA intends to exercise enforcement discretion while manufacturers prepare and submit their 510(k). FDA would expect sunlamp products marketed during the 1 year period to comply with all special controls by the time the period expires.
- Individual sunlamp products that have been shipped to operators or users such as salons and individual consumers *before* the effective date of a final order: FDA would expect manufacturers to provide updated labeling that complies with the labeling special controls in proposed § 878.4635(b)(6) (21 CFR 878.4635(b)(6)) to operators or users within 1 year of the effective date of a final order.

[2] See FDA's guidance, ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' (available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm*), for additional guidance on whether a device change or modification requires a 510(k) submission.

IX. Environmental Impact

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

X. Paperwork Reduction Act of 1995

This proposed order refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

In addition, FDA concludes that the labeling statements in proposed § 878.4635(b)(6)(i), (b)(6)(iii), and (b)(6)(iv) do not constitute a ''collection of information'' under the PRA. Rather, the labeling statements are ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2)).

XI. Proposed Effective Date

FDA proposes that any final administrative order based on this proposal become effective 90 days after its date of publication in the **Federal Register**. Please see section VIII, ''Implementation Strategy,'' for projected dates by which FDA will expect 510(k) submissions and conformance to special controls.

XII. Comments

Interested persons may submit either electronic comments regarding this order to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). FDA is explicitly seeking comment on the following issues:

- Whether FDA should consider additional special controls or other regulatory requirements to mitigate the risks posed by sunlamp products.
- FDA's proposed implementation strategy. In particular, what is the most practical method for manufacturers of devices currently on the market to conform to the labeling special control in proposed § 878.4635(b)(6) before 1 year after the effective date of the final order?

It is necessary to send only one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m. Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

XIII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in § 878.4635 related to the classification of UV lamps for tanning as class I devices and to codify the reclassification of sunlamp products into class II.

XIV. References

FDA has placed the following references on display in the Division of Dockets Management (see **ADDRESSES**). Interested persons may see them 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 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4635 is revised to read as follows:

§ 878.4635 Sunlamp product.

(a) *Identification.* An electronic product that includes one or more ultraviolet (UV) lamps and a fixture 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. This definition includes tanning beds, tanning booths, and UV lamps (bulbs) sold separately.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Conduct performance testing that demonstrates the following:

(i) Sunlamp products meet appropriate output performance specifications such as wavelengths, energy density, and lamp life; and

(ii) Safety features, such as timers to limit UV exposure and alarms, function properly.

(2) Demonstrate that sunlamp products are mechanically safe to prevent user injury.

(3) Demonstrate software verification, validation, and hazard analysis.

(4) Demonstrate that sunlamp products are biocompatible.

(5) Demonstrate that sunlamp products are electrically safe and electromagnetically compatible in their intended use environment.

(6) Labeling must bear all information required for the reasonable assurance of safe and effective use of the device.

(i) The warning statement below must appear on all sunlamp product fixtures. This statement must be permanently affixed or inscribed on the product when fully assembled for use so as to be legible and readily accessible to view by the person who will be exposed to UV radiation immediately before the use of the product. It shall be of sufficient durability to remain legible throughout the expected lifetime of the product. It shall appear on a part or panel displayed prominently under normal conditions of use so that it is readily accessible to view whether the tanning bed canopy (or tanning booth door) is open or closed when the person who will be exposed approaches the equipment and the text shall be at least 10 millimeters (height). Labeling on the device must include the following statement:

''Attention: This sunlamp product should not be used on persons under the age of 18 years.''

(ii) Manufacturers of sunlamp products shall provide or cause to be provided in the user instructions for a sunlamp product as well as all catalogs, specification sheets, and descriptive brochures intended for consumers in which sunlamp products are offered for sale, and on all consumer-directed Web pages on which sunlamp products are offered for sale, the following contraindication and warning statements:

(A) ''Contraindication: This sunlamp product is contraindicated for use on persons under the age of 18 years.''

(B) ''Contraindication: This sunlamp product must not be used if skin lesions or open wounds are present.''

(C) ''Warning: This sunlamp product should not be used on individuals who have had skin cancer or have a family history of skin cancer.''

(D) ''Warning: Persons repeatedly exposed to ultraviolet sunlamp products should be regularly evaluated for skin cancer.''

(iii) Manufacturers of sunlamp products shall provide validated instructions on cleaning and disinfection of sunlamp products between uses in the user instructions.

(c) Sunlamp products are subject to the electronic product performance standard at § 1040.20 of this chapter.

Dated: May 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10982 Filed 5–6–13; 4:15 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

33 CFR Part 334

Pacific Ocean Off the Kekaha Range Facility at Barking Sands, Island of Kauai, Hawaii; Danger Zone

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Corps of Engineers is proposing to amend its regulations to establish a new danger zone in waters of the Pacific Ocean off the Kekaha Range Facility, Barking Sands, Island of Kauai, Hawaii. The proposed amendment is necessary for the Hawaii Army National Guard to continue small arms training operations at the Kekaha Range Facility and to protect the public from potentially hazardous conditions which may exist as a result of that use. The proposed amendment would prohibit, on an intermittent basis, vessels from entering a six mile wide section of the Pacific Ocean that narrows to a 0.7 mile wide section along the shoreline fronting the Kekaha Range Facility without first obtaining permission from the Commanding Officer of Kekaha Range Facility.

DATES: Written comments must be submitted on or before June 10, 2013.

ADDRESSES: You may submit comments, identified by docket number COE–2013–0004, by any of the following methods:

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

Email: david.b.olson@usace.army.mil. Include the docket number COE–2013–0004, in the subject line of the message.

Mail: U.S. Army Corps of Engineers, Attn: CECW–CO–R (David B. Olson), 441 G Street NW., Washington, DC 20314–1000.

Hand Delivery/Courier: Due to security requirements, we cannot receive comments by hand delivery or courier.

Instructions: Direct your comments to docket number COE–2013–0004. All