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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 and Ultraviolet Lamps Intended for Use in Sunlamp Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final Order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reclassifying 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 renaming them sunlamp products and UV lamps intended for use in sunlamp products. FDA is designating special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is reclassifying this device on its own initiative based on new information.

DATES: This order is effective September 2, 2014. See further discussion in section V ''Implementation Strategy'' for compliance dates.

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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, rather than through the administrative order procedures that apply to this 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.

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 (f)(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.) FDA issued a proposed reclassification order for the devices that are the subject of this final reclassification order on May 9, 2013 (78 FR 27117).

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 (D.C. 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, including sunlamp products

and UV lamps intended for use in sunlamp 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. Sunlamp products and UV lamps intended for use in 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 and UV lamps intended for use in 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 and UV lamps intended for use in 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 product and UV lamp 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).

II. Public Comments in Response to the Proposed Order

FDA received over 2,500 comments in response to the proposed order. Many of these comments supported the proposal. The comments that expressed concerns raised many of the same issues as one another. The comments can be categorized in the following six areas: (1) Terminology and definitions, (2) procedural aspects of the classification, (3) 510(k) notification, (4) special controls, (5) underlying science, and (6) miscellaneous comments. To make it easier to identify comments and our response to the comments, the word ''Comment'' appears before the description of the comment, and the word ''Response'' appears before our response. We have also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. Terminology and Definitions

(Comment 1) Why is the Agency using such a broad interpretation of the term ''sunlamp product'' that includes sunlamp products and UV lamps? The Agency's treatment of these products as a single class of product is inconsistent with the performance standard at § 1040.20, which identifies them as distinct products. By treating them as a single class of product, FDA is ignoring differences in physical characteristics between these products.

(Response 1) Prior to this reclassification, UV lamps intended to tan the skin and sunlamp products incorporating UV lamps were regulated together under the same classification regulation, § 878.4635 (21 CFR 878.4635), as class I 510(k)-exempt devices (subject to the limitations in 21 CFR 878.9, *Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act*). Manufacturers appear to have understood that this classification included both sunlamp products and UV lamps, since they have been listing both products under the same product code in the Agency's Registration and Listing database.[1]

In the proposed reclassification order, FDA proposed to rename the classification regulation from ''ultraviolet lamps for tanning'' to ''sunlamp products,'' but after considering comments submitted in response to the proposed order, FDA believes the proposed renaming would not be sufficiently clear in its inclusion of both sunlamp products and UV lamps intended for use in sunlamp products. Thus, in this final order, FDA has renamed the regulation and revised the definition of the product in § 878.4635(a) to more clearly indicate that the regulation includes both sunlamp products and UV lamps intended for use in sunlamp products. This language is consistent with the terminology used in the performance standard for these products in § 1040.20.

FDA acknowledges that there are differences between sunlamp products and UV lamps intended for use in sunlamp products, and so has made clear in this final order that certain labeling requirements (see § 878.4635(b)(6)(i)) apply only to sunlamp products whereas other labeling requirements (see § 878.4635(b)(6)(ii)) apply to both sunlamp products and and UV lamps intended for use in sunlamp products. Further, FDA is requiring that the labeling special control at § 878.4635(b)(6)(i)(A) be placed in a black box. For devices that have significant risks that would make the devices unsafe if used inappropriately, FDA may require that the risks be explained in warning statements placed in a black box that is displayed prominently in the labeling to ensure awareness by the end user. In conjunction with other regulatory controls, awareness of these important risks by the end user enables these devices to be used safely. In this case, a prominent black box warning that identifies individuals who should not use the device is necessary to allow sunlamp products to be used safely.

B. Procedural Aspects of Classification

(Comment 2) The proposed order cites several studies that were published subsequent to the March 2010 General and Plastic Surgery Advisory Panel (the ''panel''), underscoring the evolving science in this space. By not convening a new panel, is the Agency denying stakeholders a fair opportunity to address the methodology or other concerns related to studies on which the Agency is relying to take this action? Further, by failing to convene a panel, is the Agency failing to rely on up-to-date medical research?

(Response 2) The 2010 panel considered all relevant scientific issues associated with sunlamp products and UV lamps intended for use in sunlamp products and recommended upclassifying these devices. FDA is not aware of any significant changes in benefits or risks relating to sunlamp products and UV lamps intended for use in sunlamp products that have been identified in the scientific literature since the 2010 panel meeting. The articles published since that meeting offer further support for the panel's recommendation.

Of the 53 references cited in the proposed order, only 4 are scientific articles published after the 2010 panel. Although these four articles were published after the panel met to discuss reclassification of sunlamp products and UV lamps intended for use in sunlamp products, the substance therein is not ''new'' as it relates to issues considered at the 2010 panel. Specifically:

- Although Reference 1 (Reference 15 in the proposed order) was published after the panel meeting, its conclusion—that users with a history of melanoma are at an increased risk for melanoma reoccurrence—is also discussed in research published in 2006 by

[1] See *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrl/rl.cfm* product code LEJ.

Freedman, et al. (Ref. 2), which was known at the time of the panel meeting.

- References 3 and 4 (References 18 and 19 in the proposed order) discuss the effects of tanning in childhood and early adult life, which were discussed extensively by the panel. Some panel members favored an age restriction for indoor tanning (i.e., individuals under a certain age would not be permitted to use sunlamp products and UV lamps intended for use in sunlamp products) and thought that the cutoff age should be 18.
- As discussed in the proposed order, Reference 5 (Reference 28 in the proposed order) showed that, despite protective measures instituted in commercial tanning facilities, 66 percent of female college-age users reported skin erythema from indoor tanning, and these users reported one episode of sunburn out of every five tanning sessions. These findings are consistent with an earlier report (Ref. 6) (Reference 29 in the proposed order) published in 2009 that showed that 58 percent of adolescent indoor tanners had experienced sunburns from exposure to sunlamp products and UV lamps intended for use in sunlamp products.

Stakeholders had an opportunity to raise concerns relating to the underlying methodology of any studies FDA relied on in the proposed order in their comments on that proposed order. We have addressed such comments in the subsection ''*E. Underlying Science''* in this document.

(Comment 3) Using a panel meeting that took place prior to the issuance of the proposed reclassification order violates the sequence of events for issuing an administrative order to change the classification of a device as prescribed by section 513(e) of the FD&C Act, as amended by FDASIA.

(Response 3) The process followed by FDA in reclassifying these devices is in accordance with the applicable statutory provisions, which were recently amended by FDASIA. Section 608 of FDASIA amended section 513(e) of the FD&C Act by changing the reclassification process from rulemaking to an administrative order process. The amendments to section 513(e) of the FD&C Act made by FDASIA, require, in relevant part, that issuance of an administrative order reclassifying a device be preceded by a proposed order and a meeting of a device classification panel.

As amended, this section of the FD&C Act does not prescribe when these two events (the panel meeting and proposed order) must occur in relation to each other. Therefore, this provision provides the Agency with the flexibility to hold a panel meeting either before or after the issuance of a proposed reclassification order. This approach is consistent with the prior panel provision in section 513(e), which provided for FDA, at its discretion, to secure a panel recommendation prior to the promulgation of a reclassification rule and reflects longstanding practice. Indeed, prior to FDASIA, when a panel meeting was discretionary, FDA often held a panel meeting prior to proposing reclassification of a device, for example, when the Agency determined that a recommendation from the panel would help inform whether proposing reclassification for the device was appropriate. FDA believes its interpretation of section 513(e), as amended by FDASIA, is reasonable and allows the Agency to carry out the reclassification of devices in the most efficient and effective manner for the Agency and all stakeholders.

FDA believes the panel's deliberations and recommendations from the meeting held in March 2010 concerning potential changes to the current classification or regulatory controls for sunlamp products and UV lamps intended for use in sunlamp products remain relevant and fully satisfy the requirements in section 513(e) of the FD&C Act. As explained in the proposed reclassification order (Ref. 7), ''No significant changes in risks relating to [sunlamp products and UV lamps intended for use in 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.'' Therefore, convening another panel meeting on the reclassification of sunlamp products and UV lamps intended for use in sunlamp products would be unnecessarily duplicative and an inefficient use of the time and resources of all relevant parties.

(Comment 4) Comments were submitted to the record in connection with the 2010 panel meeting, including a scientific critique of the scientific papers on which FDA had relied. FDA's proposed order fails to address or discuss the scientific submissions made by the stakeholders. Did FDA take these submissions into account, and, if so, how were they addressed in the proposed order?

(Response 4) Stakeholders submitted 139 comments to the docket for the 2010 panel meeting (Docket No. FDA–2009–N–0606). Although FDA's proposed order does not directly discuss each specific comment, the Agency did review and consider all received comments in the development of its proposed reclassification of sunlamp products and ultraviolet lamps intended for use in sunlamp products. The proposed order includes the following summary of the comments ''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 (Ref. 7).''

FDA considered not only the comments received in the docket to the 2010 panel meeting, but also relevant scientific literature, both in favor of and against the use of sunlamp products. As required by section 513(e) of the FD&C Act, as amended by FDASIA, the proposed order provided a substantive summary of the valid scientific evidence concerning the proposed reclassification of the device, including the available information on the benefits of use of sunlamp products, as well as the risks to health from use of these products. The proposed order also called for comments from any interested stakeholders. The comment period on the proposed order closed on August 7, 2013. All comments received were considered by the Agency prior to development of this final reclassification order.

(Comment 5) The 2010 panel was not representative of industry and certain members of the panel had a conflict of interest because they were partnered with the American Academy of Dermatology (AAD).

(Response 5) Advisory committees provide FDA with independent advice from outside experts. FDA's advisory committee program is governed by a number of Federal laws and regulations that set forth standards for convening advisory committees and reviewing potential conflicts of interest. FDA remains committed to ensuring that its advisory committee process is conducted according to applicable statutes and regulations and consistent with relevant FDA guidance. These laws, regulations, and guidance documents are available on our Web site, and provide ready access to the statutory and regulatory framework that FDA advisory committees operate

within and describe the steps that FDA has taken to enhance decisionmaking, increase transparency, and strengthen public confidence in our advisory committee program.

FDA disagrees with the comment that the composition of the 2010 panel was flawed. A copy of the panel roster can be found at the FDA's Web site (Ref. 8). The 2010 panel members were screened for potential or actual conflicts of interest in accordance with legal requirements and consistent with FDA guidance, and were cleared by the Agency to participate at the meeting.[2] As indicated on the panel roster, there was a consumer representative, an industry representative, and a patient representative on the 16-person panel.

(Comment 6) Prior to the 2012 enactment of FDASIA, classifications under section 513(e) of the FD&C Act were governed by the Federal rulemaking process requiring economic analysis of any proposed regulations. At any time after the Agency commenced its reclassification efforts with respect to sunlamp products and UV lamps intended for use in sunlamp products in 2009, did the Agency undertake any formal or informal economic analysis of possible changes to the regulation of this product?

(Response 6) The Federal rulemaking process requires economic analysis of proposed rules under Executive Order 12866. Section 608 of FDASIA amended section 513(e) of the FD&C Act by changing the reclassification process from rulemaking to an administrative order process. This order process is not subject to Executive Order 12866. Therefore, although the Agency considered the impact on stakeholders and the least burdensome method to secure a reasonable assurance of safety and effectiveness for sunlamp products and UV lamps intended for use in sunlamp products, the Agency has not conducted an economic analysis for reclassification of these devices.

FDA did consider the impact that this reclassification may have on small businesses and has decided to employ a staged implementation plan to minimize the burden on affected entities. Small businesses play an important role in the medical device industry and are responsible for more than half of all medical devices under development, including sunlamp products and UV lamps intended for use in sunlamp products. Given this role, FDA recognizes how critical it is that small firms understand the regulatory landscape in order to meet regulatory requirements for marketing. The Division of Industry and Consumer Education (DICE) in the Center for Devices and Radiological Health (CDRH) is dedicated to helping small businesses successfully navigate the Agency's device approval and clearance processes. In addition, small businesses may qualify for substantially discounted user fees—a 510(k) submission fee for a small business in FY 2014 is $2,585, which is half the standard 510(k) submission fee.

(Comment 7) Because FDA has not disclosed what the Agency will ultimately require under amendments to § 1040.20, industry cannot adequately comment on the proposed reclassification order.

(Response 7) Manufacturers must comply with the requirements set forth in § 1040.20. If, in the future, § 1040.20 is updated, as FDA has announced its intent to do, it will be done through its own notice and comment rulemaking process and stakeholders will be provided the opportunity to comment during that process.

(Comment 8) FDA should update the requirements in § 1040.20 prior to the implementation of this reclassification because 510(k)s for these products that are submitted prior to the performance standard amendments would not necessarily comply with the performance standard and could require manufacturers to have to submit additional 510(k)s for their products.

(Response 8) With respect to § 1040.20, manufacturers must comply with the performance standard in effect at the time of the 510(k) submission. If the performance standard is amended, manufacturers would not need to submit a new 510(k) unless there are significant changes to the device that trigger the need for a new 510(k) submission under 21 CFR 807.81(a)(3) (see FDA's guidance ''Deciding When to Submit a 510(k) for a Change to an Existing Device'' (*http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm*)).

C. 510(k) Notification

(Comment 9) Has FDA conducted any analysis of the increased resources it will need to enforce these new regulations, including the demands placed on the Agency to review 510(k) premarket notifications?

(Response 9) A review of FDA's Establishment Registration and Device Listing database, which identifies, among other things, manufacturers that are registered to market medical devices and the devices that they currently market, shows that there are approximately 25 firms registered as sunlamp product manufacturers or manufacturers of UV lamps intended for use in sunlamps products. To continue offering these devices for sale, a 510(k) must be submitted by August 26, 2015, (see further discussion in section V ''Implementation Strategy''). Thus, FDA expects to receive approximately 25 510(k) submissions within this timeframe (and potentially a few other 510(k) submissions for new sunlamp products and UV lamps intended for use in sunlamp products). FDA typically receives and reviews approximately 4,000 510(k) submissions each year, so the Agency does not expect the reclassification of sunlamp products and UV lamps intended for use in sunlamp products to significantly affect review times or resources.

As a part of the Medical Device User Fee Amendments of 2012, or MDUFA III, FDA committed to meeting certain review times for 510(k) submissions. FDA's current review goal for 510(k) submissions is to make a substantial equivalence determination within 90 days of active FDA review. The latest published review data from January 29, 2014, shows that FDA has met its review goal for 100 percent of the 510(k) submissions received in fiscal year 2014, to date. FDA expects to meet these review goals for any 510(k) submission for sunlamp products or UV lamps intended for use in sunlamp products (Ref. 9).

(Comment 10) Can the Agency clarify by when it expects manufacturers to submit a 510(k) notification for products already being offered for sale, and whether those products can continue to be offered for sale after submission of the 510(k) notification but prior to Agency clearance?

(Response 10) Manufacturers of sunlamp products or UV lamps intended for use in sunlamp products that are offered for sale prior to September 2, 2014, must submit a 510(k) and comply with the labeling special controls established in this final order by August 26, 2015, which is 15 months from the date of publication of this final order (see section V ''Implementation Strategy'') for any device they wish to continue offering for sale. Manufacturers can continue offering these products for sale while FDA reviews the 510(k) submissions. However, if a 510(k) is not submitted or the device is not in compliance with the labeling special controls by this date, or if FDA determines after review of the 510(k) that the device is not substantially equivalent to a legally marketed predicate device or the device is not in compliance with the labeling

[2] See *http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125646.pdf.*

or other special controls, the device, including individual devices already in use, would be adulterated and misbranded under sections 501(f)(1)(B) and 502(o) of the FD&C Act, and the manufacturer would have to cease offering the device for sale.

(Comment 11) The proposed order is silent on the status of products that are already on the market for which the manufacturer is no longer in business or for which it is not economically viable for the manufacturer to incur the costs associated with submitting a 510(k).

(Response 11) Individual sunlamp products that have already been sold to end users prior to September 2, 2014, the model of which has been discontinued or is otherwise no longer marketed after this date, do not have to have 510(k)s or comply with the non-labeling special controls, but they must comply with the labeling special controls at § 878.4635(b)(6)(i)(A) by August 26, 2015. If the manufacturer is no longer in business, sunlamp product owners would have to apply the required labeling to sunlamp products to keep these devices in compliance with the labeling requirements.

(Comment 12) Is one 510(k) required for a ''sunlamp product,'' which by definition includes a fixture and UV lamp, or are separate 510(k)s required for the sunlamp product and UV lamp? Similarly, if UV lamps are sold with a sunlamp product and on their own, do multiple 510(k)s need to be submitted?

(Response 12) In this final order, FDA has revised the classification identification to expressly include ''sunlamp products'' and ''UV lamps intended for use in sunlamp products'' and has included revised definitions of these devices, as discussed in response to Comment 1. A 510(k) submission is required for sunlamp products and for UV lamps intended for use in sunlamp products. If a UV lamp intended for use in a sunlamp product is sold with a sunlamp product or they are sold separately from one another, then both devices can be included in the same 510(k) submission. For more information on this issue, please see FDA Guidance, ''Bundling Multiple Devices or Multiple Indications in a Single Submission,'' available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089731.htm*.

(Comment 13) If FDA is requiring that UV lamp manufacturers submit 510(k)s for their lamps, are lamp manufacturers required to submit separate 510(k)s for use of their lamps in each tanning bed or booth? Or, can UV lamp manufacturers that are required to submit 510(k)s for their lamps do so without referencing use of the lamp with a particular tanning bed or booth? Is a replacement UV lamp manufacturer required to submit a separate 510(k) for use of each replacement lamp type in each possible tanning bed or tanning booth in which the replacement lamp could conceivably be used?

(Response 13) Manufacturers of UV lamps that submit a 510(k) do not need to submit a separate 510(k) for use of each replacement lamp type in each possible tanning bed or tanning booth in which the replacement lamp could conceivably be used, but they should specify in their 510(k) submission the design characteristics of the sunlamp product with which the lamp is compatible.

(Comment 14) If FDA is requiring that all UV lamp manufacturers, including replacement lamp manufacturers, submit 510(k)s, is a manufacturer of replacement UV lamps required to submit a separate 510(k) for each of its lamp types? Will the Agency accept 510(k)s for lamp model families?

(Response 14) Instead of submitting separate 510(k)s for different lamp types, a manufacturer can submit a ''bundled'' 510(k) for related lamps. For more information on this issue, please see FDA Guidance, ''Bundling Multiple Devices or Multiple Indications in a Single Submission,'' available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089731.htm*.

(Comment 15) Sunlamp product and UV lamp manufacturers are aware of cleared 510(k)s for ''UV lamps for tanning,'' but at least some of these 510(k)s are over 20 years old. Over the past 20 years, sunlamp products and UV lamps have improved substantially with regard to performance and safety. Sunlamp product and UV lamp manufacturers are uncertain how to show substantial equivalence to one of the 20-year-old sunlamp products or UV lamps given these significant improvements.

(Response 15) FDA will find a contemporary sunlamp product or UV lamp intended for use in a sunlamp product to be substantially equivalent to a predicate device if the contemporary device: (1) Has the same intended use as the predicate device and (2) has the same technological characteristics as the predicate device or has different technological characteristics but is at least as safe and effective as the predicate device and does not raise new questions of safety or effectiveness. If the device has different technological characteristics from the predicate device, the 510(k) submission must include a summary of how the technological characteristics of the device compare to a legally marketed predicate device (21 CFR 807.92(a)(6)). In addition to showing substantial equivalence, manufacturers of new sunlamp products will need to show compliance with the special controls required under this order.

(Comment 16) FDA should ''grandfather'' in all currently legally marketed sunlamp products, such that they would not be subject to the requirements set forth in this order. Moreover, these products should be allowed to be used as predicate devices as long as the manufacturers provide adequate documentation that the products meet all requirements necessary for a 510(k) submission.

(Response 16) Manufacturers of sunlamp products or UV lamps intended for use in sunlamp products that are offered for sale prior to September 2, 2014, are required to submit 510(k)s and must comply with the labeling special controls by August 26, 2015, for any device they wish to continue offering for sale. Any sunlamp product or UV lamp intended for use in a sunlamp product legally marketed on or before September 2, 2014, including both 510(k)-cleared and 510(k)-exempt devices, can be used as a predicate device in a 510(k). A 510(k) for such a device must demonstrate that the device was legally offered for sale on or before September 2, 2014, and it must comply with the special controls.

D. Special Controls

(Comment 17) Many of the proposed special controls are either unrelated to UV lamps intended to be used with sunlamp products or are impossible for UV lamp manufacturers to achieve without involvement of a tanning bed or tanning booth. For example, UV lamps do not come into contact with indoor tanners due to safety issues associated with heat generation and possible lamp breakage. Given this, how would UV lamp manufacturers conduct biocompatibility testing or comply with some of the other special controls that may apply only to sunlamp products?

(Response 17) If a certain non-labeling special control does not, as a practical matter, apply to a device due to the device's nature or design, manufacturers may meet such special control by explaining such practical inapplicability in their 510(k) submission to FDA. For example, biocompatibility testing would not apply to a UV lamp that does not contact the human body and the software verification requirement would not apply to a UV lamp that does not employ software. As long as FDA finds such justification acceptable, the

manufacturer would not have to conduct or submit any testing that would otherwise be required by that particular special control. FDA has chosen this flexible approach, as opposed to assigning certain special controls to certain types of sunlamp products and UV lamps intended for use in sunlamp products, to account for ever-changing technology in this area.

(Comment 18) FDA's proposed reclassification order would require that certain warning labeling appear on ''sunlamp product fixtures.'' Given that FDA specifies that the warning must appear on ''sunlamp product fixtures,'' does this special control apply to UV lamps?

(Response 18) Based on comments we received, we have clarified the applicability of the labeling requirements in the final order. The labeling in § 878.4635(b)(6)(i) pertains only to sunlamp products while the labeling in § 878.4635(b)(6)(ii) pertains to sunlamp products and UV lamps intended for use in sunlamp products. This means that sunlamp products must comply with the requirements in § 878.4635(b)(6)(i) and (b)(6)(ii), while UV lamps intended for use in sunlamp products must comply with § 878.4635(b)(6)(ii) and not with § 878.4635(b)(6)(i).

(Comment 19) A font height of 10 millimeters (mm) is too small for the labeling prescribed in proposed § 878.4635(b)(6)(i).

(Response 19) FDA believes 10 mm is sufficient height to attract attention and warn prospective users that individuals under age 18 should not use the device. Ten mm is a minimum; labels are permitted to display font greater than 10 mm.

E. Underlying Science

(Comment 20) The recent information cited by FDA in the proposed reclassification order is comprised solely of recent reviews of information that has been available for several years, and this information does not compel a change to the current classification or performance standards.

(Response 20) The articles referenced in the proposed order qualify as ''new information'' under section 513(e) of the FD&C Act. 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 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).). The sources cited in the proposed reclassification order are all encompassed by this definition and reveal, among other things, that UV radiation is a significant contributing factor in developing skin cancer, that the number of females exposed to indoor UV radiation who are diagnosed with skin cancer is increasing, and that individuals under 18 who are exposed to UV radiation are at an increased risk of developing skin cancer. As stated in the proposed order, the cumulative effects of UV radiation exposure have been linked to higher incidence of skin cancer (Ref. 10). Moreover, individuals under 18 are particularly vulnerable to the damaging effect of UV radiation. According to a 2008 article recommending an age restriction to prevent sunlamp product use in children and teenagers, a number of biological factors are identified as potentially causing the increase in the risk of developing melanoma from exposure to sunlamps during those years (Ref. 11). These findings have compelled a change in how FDA regulates these devices.

(Comment 21) Sunlamp products can stimulate the body to produce vitamin D. In addition to bone problems and increased cancer risk, vitamin D deficiency has been linked to a heightened risk of Type 1 diabetes, multiple sclerosis and other autoimmune diseases, infectious diseases such as influenza and tuberculosis, and high blood pressure. For these reasons, additional regulation of sunlamp products is not appropriate.

(Response 21) FDA agrees that vitamin D is critical for the body's health. In the proposed order, FDA acknowledged that UV radiation stimulates the body's production of vitamin D, however, there are safer alternatives to obtain vitamin D other than the use of sunlamp products and UV lamps intended to be used in sunlamp products, for example, through an individual's diet (Ref. 12). As stated previously, FDA believes that additional regulation is necessary to provide a reasonable assurance of safety and effectiveness of these devices.

(Comment 22) FDA should not rely on the International Agency for Research on Cancer's (IARC) study (Ref. 13) to support this reclassification because that study included outdoor sun exposure and dermatology exposure, which confounded the data and exaggerated the effects of UV radiation.

(Response 22) As with most indoor tanning risk studies, it can be difficult to discern for each subject the relative amounts of indoor and outdoor UV exposure. However, previous use of a sunlamp product and frequency of use can be assessed to determine relative risk of indoor tanning exposure. All of the studies analyzed in the IARC study focused on indoor tanning and melanoma as well as other skin cancers such as basal cell carcinoma and squamous cell carcinoma. FDA believes the IARC report's conclusions are applicable to indoor tanning.

(Comment 23) Even though women's use of indoor tanning devices has increased in recent years, SEER cancer incidence data shows that the incidence of melanoma has decreased from 5.0 in 1975–1982 to 2.3 in 1981–2010 in females (Ref. 14). This finding undermines the argument that indoor tanning causes melanoma.

(Response 23) The SEER incidence data referenced in the comment is incorrect. In the SEER data, an increase in the incidence of melanoma in females has been noted since 1975 and has not abated. The age adjusted rates of melanoma for females per 100,000 are as follows (Ref. 15):

TABLE 1

Year	SEER Melanoma incidence per 100,000 females
1975	7.44
1980	9.63
1985	11.16
1990	11.84
1995	13.81
2000	15.50
2005	18.41
2010	19.30

The increase in melanoma incidence among white females is even greater (Ref. 15):

TABLE 2

Year	SEER melanoma incidence per 100,000 white females
1975	8.21
1980	11.12
1985	12.70
1990	13.93
1995	16.47
2000	19.08
2005	23.14
2010	24.23

(Comment 24) The IARC report shows only a 1/10 of 1 percent increase in risk of melanoma. The IARC report clearly

states that epidemiologic studies do not support a consistent relationship between tanning and cancer.

(Response 24) FDA is unaware of the source of the 1/10 of 1 percent value referenced by the commenter. Rather, the IARC report identified a causal relationship between indoor tanning and melanoma risk based on evidence pertaining to the strength, consistency, dose-response and temporal sequence of the association of the use of sunlamp products with melanoma risk, and of the coherence and biologic plausibility of the association (Ref. 13). Additionally, the study found that first exposure to sunlamp products before age 35 increased the risk of melanoma by 75 percent compared to individuals that never used sunlamp products.

(Comment 25) The cause of melanoma is unknown, although most scientists believe the primary cause is genetic in nature. The personal risk factors for melanoma include red hair, extremely pale skin that will not tan, presence of moles and freckles on the body, and a family history of melanoma. Upclassifying these devices, and limiting exposure to UV radiation, is not necessary for those without a genetic predisposition to melanoma.

(Response 25) Although personal risk factors can also contribute to the risk for melanoma, there have been multiple studies which have found that sunlamp product use increases the risk of melanoma. Meta analyses by Gallagher et al. (Ref. 16), IARC (Ref. 13), and Boniol et al. (Ref. 17) have all found a link between sunlamp product use and melanoma.

(Comment 26) The literature is replete with conflicting information, including science suggesting that moderate, non-burning UV exposure reduces the risk of melanoma and that sunburn is the relevant exposure circumstance to be avoided, whether the UV comes from the sun or from a tanning bed, and whether the person is older or younger than 18. Sunburn prevention as the correct approach is supported by research showing that biologically, sunburn affects the skin differently when compared to non-burning UV exposure. Sunburning should be avoided, but moderate exposure by individuals—regardless of the user's age—is not risky.

(Response 26) As stated in FDA's proposed order to reclassify these devices, there is no evidence that moderate non-burning UV exposure or attaining a ''base tan'' provides any protection against premature aging of the skin or reduces the risk of skin cancer (Ref. 7). The Agency concurs with the comment that there are other risk factors for melanoma besides sunbed use.

(Comment 27) Dr. David G. Hoel, 1 of the 20 scientists that were called upon by the IARC in 2009 to reassess the carcinogenicity of all forms of radiation, has written a report stating that the 2006 IARC conclusion that there is a 75 percent increase in melanoma risk when tanning starts before age 35 is invalid. Dr. Hoel is preparing an article for publication on the subjects of melanoma, UV radiation, and the IARC report. The purpose of this article is to correct the many misconceptions about the science regarding UV radiation and melanoma that have been promoted by the AAD and other anti-tanning advocates. Dr. Hoel argues that the significant differences between regulatory standards in the United States and Europe with regard to use of sunlamp products make the predominantly European data in the IARC report an inappropriate basis for the FDA's decision to change the controls applicable to sunlamp products in the United States.

(Response 27) The paper alluded to has not been published or undergone peer review. Studies subsequent to the IARC study have corroborated that study's findings that there is a correlation between melanoma and sunlamp product use. For example, a meta-analysis employing data from numerous studies found an increased risk of melanoma with sunlamp product use (Ref. 17). Furthermore, this study noted that the magnitude of the increased risk was greater when sunlamp product use began earlier in life. In addition, Doré and Chignol observed that two studies in Minnesota and Australia found an increased risk of melanoma with indoor tanning (Ref. 18). They also observed a very large study of Norwegian and Swedish women that found an increased risk of melanoma with indoor tanning.

(Comment 28) After further analysis of the IARC report, Dr. Mia Papas and Dr. Anne Chappelle published a peer-reviewed report (Ref. 19) criticizing the IARC report for not differentiating among Medical Phototherapy Equipment, Unsupervised Home Equipment, and Commercial Tanning Salon Equipment. Their article indicates that there is no association between sunlamp product use and melanoma if you remove home use and medical use of sunlamp products from the analysis. Therefore, the report being used to support the reclassification is flawed.

(Response 28) This literature (Ref. 19) has not been published in a peer-reviewed journal, despite the commenter's assertion to the contrary. In the peer-reviewed journal ''Cancer Epidemiology, Biomarkers & Prevention,'' Gallagher et al. (Ref. 16) noted that the results from studies subsequent to the IARC report, taken together, do not differ in character from those seen in the earlier studies. During earlier studies, home use of sunlamp products was greater than it is now. During later studies, the proportion of the sunlamp product use at indoor tanning facilities increased greatly, but according to Gallagher et al. (Ref. 16), melanoma incidence did not markedly differ, supporting the conclusion that the risk from use of sunlamp products at tanning facilities does not differ markedly from the risks of home use of such devices.

(Comment 29) An article written by William Grant (Ref. 20) indicated that the 50 subjects in the IARC report were primarily skin type 1. Skin type 1 individuals have a natural increased risk to skin cancer and because tanning facilities do not tan skin type 1's, this skewed the data in the IARC report.

(Response 29) The Grant critique (Ref. 20) points out that fair skinned individuals are more likely than other individuals to develop skin cancer due to UV exposure. However, UV radiation exposure from indoor tanning use increases the risk of skin cancer regardless of whether individuals have high or low pigmentation (Ref. 21). For this reason, FDA has not changed its position regarding the link between sunlamp product use and skin cancer. It is also important to note that a significant portion of the U.S. population is skin type 1 and may use sunlamp products (Ref. 22).

F. Miscellaneous

(Comment 30) Unless tanning beds for home use are banned, this reclassification does not make sense.

(Response 30) The commenter did not provide a justification for this conclusion, so we are not completely clear as to the basis for this comment. However, we emphasize that the new 510(k) requirements and special controls (including labeling) set forth in this final order apply to all sunlamp products and UV lamps intended to be used in sunlamp products, including ones sold to individuals for home use. FDA believes that the regulatory controls set forth in this order are necessary to provide a reasonable assurance of safety and effectiveness for these devices.

(Comment 31) Regulated tanning facilities are a safer alternative than home tanning where there are no informed workers. Tanning facility

owners are trained and educated to protect clients who want to tan.

(Response 31) This final order does not distinguish between devices sold for use at home and devices sold to tanning facilities; the regulatory controls set forth in this order apply to both.

(Comment 32) People who have prescriptions for dermatological disorders will be burdened by this reclassification.

(Response 32) Devices prescribed for individuals with dermatological disorders have been and will continue to be regulated differently from devices regulated under § 878.4635. UV lamps for dermatological disorders have long been class II medical devices regulated under 21 CFR 878.4630 and are unaffected by this reclassification.

III. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the preamble to the proposed order. FDA is issuing this final order to reclassify UV lamps used to tan the skin from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification and rename them sunlamp products and UV lamps intended for use in sunlamp products.

IV. 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 reclassification, the Agency is not exempting 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 predicate devices already legally on the market will be subject to the more rigorous premarket approval requirement.

FDA cleared several 510(k)s for sunlamp products prior to exempting the devices from premarket notification submission.[3] At least one 510(k) for a sunlamp product has been cleared since then under product code LEJ. These cleared sunlamp products, as well as any 510(k)-exempt sunlamp product or UV lamp intended for use in a sunlamp product legally offered for sale on or before September 2, 2014, can serve as predicates for substantial equivalence purposes.

V. Implementation Strategy

Based on comments on the proposed order regarding our implementation strategy, we are clarifying the compliance dates for the various requirements set forth in this final order. For additional information on this issue, see the **DATES** heading of this final order.

- Models of sunlamp products and UV lamps intended for use in sunlamp products that have not been offered for sale prior to September 2, 2014, or have been offered for sale 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:[4] Manufacturers must obtain 510(k) clearance before marketing the new or changed device.
- Models of sunlamp products and UV lamps intended for use in sunlamp products that have been offered for sale prior to September 2, 2014, and continue to be offered for sale after this date: Manufacturers must submit a 510(k) and comply with labeling special controls by August 26, 2015, for any device they wish to continue offering for sale. If a 510(k) is not submitted by this date or the device is not in compliance with the labeling special controls or if FDA determines after review of the 510(k) that either the device is not substantially equivalent to a legally marketed predicate or the device is not in compliance with the labeling or other special controls, the device model would be adulterated and misbranded, and offering the device for sale would have to cease.
- Individual sunlamp products that have been shipped to operators or users such as tanning facilities and individual consumers prior to September 2, 2014, the model of which has been discontinued or is otherwise no longer offered for sale: These devices must comply with the labeling special controls at § 878.4635(b)(6)(i)(A) by August 26, 2015. If the manufacturer is no longer in business, sunlamp product owners would have to apply the required labeling to keep these devices in compliance with the labeling requirements.

[3] See 59 FR 63005 (December 7, 1994).

[4] 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.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this 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.

VII. Paperwork Reduction Act of 1995

This final 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 § 878.4635(b)(6)(i)(A) and (b)(6)(ii)(A) through (b)(6)(ii)(D) 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)).

VIII. 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 final order, we are revoking the requirements in

§ 878.4635 related to the classification of UV lamps for tanning as class I devices and codifying the reclassification of sunlamp products and UV lamps intended for use in sunlamp products into class II.

IX. References

FDA has placed the following references on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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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3. Reed, K.B., J.D. Brewer, C.M. Lohse, et al., ''Increasing Incidence of Melanoma Among Young Adults: An Epidemiological Study in Olmsted County, Minnesota,'' *Mayo Clinic Proceedings,* vol. 87, pp. 328–334, 2012.
4. Cust, A.E., B.K. Armstrong, C. Goumas, et al., ''Sunbed Use During Adolescence and Early Adulthood Is Associated With Increased Risk of Early-Onset Melanoma,'' *International Journal of Cancer,* vol. 128, pp. 2425–2435, 2011.
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7. 78 FR 27117, May 9, 2013.
8. *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/GeneralandPlasticSurgeryDevicesPanel/UCM205686.pdf.*
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12. National Institutes of Health, Office of Dietary Supplements, ''Dietary Supplement Fact Sheet: Vitamin D'' (*http://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional*).
13. ''IARC Working Group on Artificial Ultraviolet Light (UV) and Skin Cancer: The Association of Use of Sunbeds With Cutaneous Malignant Melanoma and Other Skin Cancers: A Systematic Review,'' *International Journal of Cancer,* vol. 120, pp. 1116–1122, 2006.
14. SEER Stat Fact Sheets: Melanoma of the Skin, *http://seer.cancer.gov/statfacts/html/melan.html#incidence-mortality.*
15. SEER Cancer Statistics Review 1975–2010, *http://seer.cancer.gov/csr/1975_2010/browse_csr.php?sectionSEL=16&pageSEL=sect_16_table.05.html.*
16. Gallagher, R.P., J.J. Spinelli, and T.K. Lee, ''Tanning Beds, Sunlamps, and Risk of Cutaneous Malignant Melanoma,'' *Cancer Epidemiology, Biomarkers & Prevention,* vol. 14(3), pp. 562–566, 2005.
17. Boniol, M., P. Autier, P. Boyle, et al., ''Cutaneous Melanoma Attributable to Sunbed Use: Systematic Review and Meta-Analysis,'' *British Medical Journal,* vol. 345, p. e4757 July 24, 2012.
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21. Zhang, M., A.A. Qureshi, A.C. Geller, et al., ''Use of Tanning Beds and Incidence of Skin Cancer,'' *Journal of Clinical Oncology,* vol. 30, pp. 1588–1593, 2012.
22. Mayer, J.A., S.I. Woodruff, D.J. Slymen, et al., ''Adolescents' Use of Indoor Tanning: A Large-Scale Evaluation of Psychosocial, Environmental, and Policy-Level Correlates,'' *American Journal of Public Health,* vol. 101(5), pp. 930–938, 2011.

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, 21 CFR part 878 is 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 products and ultraviolet lamps intended for use in sunlamp products.

(a) *Identification.* A sunlamp product is any device 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. This definition includes tanning beds and tanning booths. A UV lamp intended for use in sunlamp products is any lamp that produces UV radiation in the wavelength interval of 200 to 400 nanometers in air.

(b) *Classification.* Class II (special controls). The special controls for sunlamp products and UV lamps intended for use in sunlamp products are:

(1) Conduct performance testing that demonstrates the following:

(i) Device meets appropriate output performance specifications such as wavelengths, energy density, and lamp life; and

(ii) Device's safety features, such as timers to limit UV exposure and alarms, function properly.

(2) Demonstrate that device is mechanically safe to prevent user injury.

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

(4) Demonstrate that device is biocompatible.

(5) Demonstrate that device is electrically safe and electromagnetically compatible in its intended use environment.

(6) *Labeling*—(i) *Sunlamp products.* (A) The warning statement below must appear on all sunlamp products and must be placed in a black box. 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.

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

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

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

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

(C) ''Warning: This 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 UV radiation should be regularly evaluated for skin cancer.''

(c) *Performance standard.* Sunlamp products and UV lamps intended for use in sunlamp products are subject to the electronic product performance standard at § 1040.20 of this chapter.

Dated: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12546 Filed 5–29–14; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 613

Federal Highway Administration

23 CFR Part 450

[Docket No. FTA–2013–0029]

Policy Guidance on Metropolitan Planning Organization (MPO) Representation

AGENCIES: Federal Transit Administration (FTA) and Federal Highway Administration (FHWA), DOT.

ACTION: Policy guidance.

SUMMARY: The FTA and FHWA are jointly issuing this guidance on implementation of provisions of the Moving Ahead for Progress in the 21st Century Act (MAP–21), that require representation by providers of public transportation in each metropolitan planning organization (MPO) that serves a transportation management area (TMA) no later than October 1, 2014. The purpose of this guidance is to assist MPOs and providers of public transportation in complying with this new requirement.

DATES: Effective June 2, 2014.

FOR FURTHER INFORMATION CONTACT: Dwayne Weeks, FTA Office of Planning and Environment, telephone (202) 366–4033 or *Dwayne.Weeks@dot.gov;* or Harlan Miller, FHWA Office of Planning, telephone (202) 366–0847 or *Harlan.Miller@dot.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

The FTA and FHWA are jointly issuing this policy guidance on the implementation of 23 U.S.C. 134(d)(2)(B) and 49 U.S.C. 5303(d)(2)(B), as amended by sections 1201 and 20005 of MAP–21, Public Law 112–141, which require representation by providers of public transportation in each MPO that serves an area designated as a TMA by October 1, 2014.[1] A TMA is defined as an urbanized area with a population of over 200,000 individuals as determined by the 2010 census, or an area with a population of fewer than 200,000 individuals that is designated as a TMA by the request of the Governor and the MPO designated for the area.[2] As of the date of this guidance, of the approximately 420 MPOs throughout the Nation, approximately 210 MPOs serve an area designated as a TMA. The FTA and FHWA will issue a joint notice of proposed rulemaking to amend 23 CFR part 450 and 49 CFR part 613 to make these planning regulations consistent with these and other current statutory requirements. Once FTA and FHWA issue a final rule amending the planning regulations, MPOs must comply with the requirements in those regulations.

To increase the accountability and transparency of the Federal-aid highway and Federal transit programs and to improve project decisionmaking through performance-based planning and programming, MAP–21 establishes a performance management framework. The MAP–21 requires FHWA to establish, through a separate rulemaking, performance measures and standards to be used by States to assess the condition of the pavements and bridges, serious injuries and fatalities, performance of the Interstate System and National Highway System, traffic congestion, on-road mobile source emissions, and freight movement on the Interstate System.[3] The MAP–21 also requires FTA to establish, through separate rulemakings, state of good repair and safety performance measures, and requires each provider of public transportation to establish performance targets in relation to these performance measures.[4]

To establish performance targets that address these performance measures, States and MPOs must coordinate their targets with each other to ensure consistency, to the maximum extent practicable.[5] For transit-related performance targets, States and MPOs must coordinate their targets relating to safety and state of good repair with providers of public transportation to ensure consistency with other performance-based provisions applicable to providers of public transportation, to the maximum extent practicable.[6] An MPO must describe in its metropolitan transportation plans the performance measures and targets used to assess the performance of its transportation system.[7] Statewide and metropolitan transportation

[1] ''Not later than 2 years after the date of enactment of the Federal Public Transportation Act of 2012, each metropolitan planning organization that serves an area designated as a transportation management area shall consist of . . . officials of public agencies that administer or operate major modes of transportation in the metropolitan area, including representation by providers of public transportation.'' 49 U.S.C. 5303(d)(2)(B). See also 23 U.S.C. 134(d)(2)(B).

[2] 23 U.S.C. 134(k)(1); 49 U.S.C. 5303(k)(1).

[3] 23 U.S.C. 150(c).

[4] 49 U.S.C. 5326(b), (c), 5329(b), (d).

[5] 23 U.S.C. 134(h)(2); 49 U.S.C. 5303(h)(2).

[6] 23 U.S.C. 134(h)(2); 49 U.S.C. 5303(h)(2).

[7] 23 U.S.C. 134(i)(2)(B); 49 U.S.C. 5303(i)(2)(B).