



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA-2015-N-1765]

RIN 0910-AH14

General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products; Withdrawal of Proposed Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of the proposed rule titled “General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products,” which published in the *Federal Register* of December 22, 2015. FDA is taking this action because it no longer intends to finalize the proposed rule.

DATES: The proposed rule published on December 22, 2015 (80 FR 79493) is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Daniel Schieffer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5562, Silver Spring, MD 20993-0002, 301-796-3350, daniel.schieffer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of December 22, 2015 (80 FR 79493), FDA (the Agency or we) issued a proposed rule titled “General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products” (the Proposed Rule).

Sunlamp products are both “devices” under section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(h)(1)) and “electronic products” under section 531(2) of the FD&C Act (21 U.S.C. 360hh(2)). They are designed to incorporate one or more ultraviolet (UV) lamps intended for irradiation of any part of the living human body, by UV radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning (see §§ 878.4635(a) and 1040.20(b)(9) (21 CFR 878.4635(a) and 1040.20(b)(9))). Sunlamp products include tanning beds and tanning booths. Sunlamp products as defined in the Proposed Rule did not include ultraviolet lamps for dermatological disorders regulated under 21 CFR 878.4630.

FDA has undertaken several regulatory initiatives related to sunlamp products. Previously, in a final reclassification order that we issued on June 2, 2014 (79 FR 31205), FDA reclassified sunlamp products and UV lamps intended for use in sunlamp products from class I to class II, making them subject to premarket notification (510(k)) requirements, and established special controls under the device authorities of the FD&C Act. The special controls consist of, among other requirements, performance testing and labeling requirements, including a warning that sunlamp products should not be used on persons under the age of 18 years. That order was effective on September 2, 2014.

Second, in a proposed rule issued simultaneously with the Proposed Rule, FDA proposed amendments to the sunlamp products and UV lamps performance standard at 21 CFR 1040.20, which includes technical and labeling requirements issued in large part under the electronic product radiation control provisions of the FD&C Act (80 FR 79505). Those proposed amendments, if finalized, would update the electronic product performance standard to reflect current science and harmonize with certain consensus standards. FDA’s proposed amendments to the sunlamp products and UV lamps performance standard at 21 CFR 1040.20 are not affected by this withdrawal.

Finally, in the Proposed Rule, FDA proposed to establish device restrictions under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)), which authorizes FDA to issue regulations

imposing restrictions on the sale, distribution, or use of a device. The Proposed Rule contained three types of proposed restrictions on the use of sunlamp products. First, the Proposed Rule proposed restricting the use of sunlamp products to individuals age 18 and older under proposed § 878.4635(c)(1). Second, in proposed § 878.4635(c)(4), the Proposed Rule proposed requiring tanning facilities to only allow adults to use a sunlamp product if the prospective user had signed a risk acknowledgement certification in the past six months, and proposed the form of this certification. Third, the Proposed Rule contained two proposed user-manual related provisions. In proposed § 878.4635(c)(2), the Proposed Rule proposed requiring tanning facility operators to provide a sunlamp product's user manual to users or prospective users of sunlamp products upon request, and in proposed § 878.4635(c)(3), the Proposed Rule proposed requiring 510(k) holders to provide a sunlamp product's user manual to tanning facility operators and sunlamp product users or prospective users upon request.

FDA received more than 8,100 comments on the Proposed Rule from entities including industry associations, medical and healthcare professional associations, law firms, cancer advocacy groups, and other interested parties, including individuals. In general, the comments discussed the dangers of UV radiation from sunlamp products; scientific aspects of the Proposed Rule; vulnerability of young people to the risks of sunlamp products; support for personal choice and parental decision-making; availability and relative safety of sunlamp product alternatives; and compliance burdens on small businesses.

In light of the scientific and technical concerns raised in the comments on the Proposed Rule, concerns regarding possible unintended consequences of certain proposals in the Proposed Rule, and potential alternatives proposed in comments received on the Proposed Rule, FDA is withdrawing the Proposed Rule in order to reconsider the best means for addressing the issues covered by the Proposed Rule and related issues regarding access to sunlamp products.

Therefore, effective on the date of publication of this document, the Proposed Rule is withdrawn.

FDA continues to consider regulatory initiatives related to sunlamp products. The withdrawal of the Proposed Rule does not preclude the Agency from reinstating rulemaking concerning the issues addressed in the proposal. Should we decide to undertake such rulemaking in the future, we will issue a proposed rule and provide a new opportunity for comment. Furthermore, this withdrawal is only intended to address the Proposed Rule “General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products” published in the *Federal Register* of December 22, 2015, and not any other pending proposals that the Agency has issued or is considering. If you need additional information about the subject matter of the withdrawn Proposed Rule, you may review the Agency’s website (www.fda.gov) for any current information on the matter.

Robert F. Kennedy, Jr.,
Secretary,
Department of Health and Human Services.
[FR Doc. 2026-05103 Filed: 3/13/2026 8:45 am; Publication Date: 3/16/2026]