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To: Tanning Registrants

From: David M. Howe, Program Director

Radiation Protection Services

Subject: Food and Drug Administration's (FDA) Safety Communication Regarding Repair and Maintenance of Tanning Beds and Booths

The Center for Health Protection, Radiation Protection Services (RPS) is releasing this bulletin regarding the FDA's safety communication which complements the State of Oregon Administrative Rules (OAR) for the need of proper maintenance and repair of tanning equipment to protect the health and safety of tanning clients.

As we return to some sense of normalcy in this time of the Covid-19 pandemic, RPS continues to maintain regulations to assure that all OARs regarding the maintenance of tanning devices are being followed. As such, RPS is placing an emphasis on the safety and maintenance of the registrant's tanning devices.

Below is a copy of a bulletin issued on July 22, 2020 by the FDA. The bulletin can be downloaded at FDA's website by accessing the 2020 Safety Communications at: https://www.fda.gov/medical-devices/safety-communications/2020-safety-communications.

The FDA monitors reports of adverse events and other problems with medical devices and alerts the public when needed to ensure proper use of devices and protect the health and safety of patients and users. The FDA is issuing this safety communication to provide information to owners and operators of tanning beds and tanning booths about the importance of repairs and preventive maintenance. This information is timely as some states and communities reopen businesses during the COVID-19 pandemic.

The U.S. Food and Drug Administration (FDA) is reminding owners and operators about repair and maintenance of tanning beds and booths. Owners and operators of tanning beds and booths should perform maintenance recommended by product manufacturers to reduce risk of smoke and fire.

Important Recommendations for Owners and Operators:

Follow the manufacturer's instructions or product manual to ensure proper use of your tanning bed or booth;

Follow the preventive maintenance schedule recommended by your tanning bed or booth product's manufacturer;

Use only lamps and replacement parts recommended in the product manual. Each tanning bed or booth should have an attached sticker that lists compatible replacement lamps; and If your tanning bed or booth is not working properly, you should not use it until it is serviced as recommended in the product manual.

Device Description

Tanning beds and booths are sunlamp products used for indoor ultraviolet (UV) tanning of the skin. Tanning beds are used while lying down and tanning booths are used while standing. These sunlamp products may include one or more UV lamps with different levels of energy output and radiation at different wavelengths to induce skin tanning.

Risk of Fire with Tanning Beds and Booths

The FDA has received 11 medical device reports of smoke or fire with tanning beds or booths in a two-year period that appear to be associated with improper maintenance, including not replacing bulbs as indicated in the user manual, dirty air filters blocking air flow, units repaired with incompatible parts, and failure to perform servicing and maintenance recommended by the product manufacturer. Although there was one report of smoke while a tanning booth was occupied, there have been no reports of injuries to users.

Following preventive maintenance instructions provided in the manufacturer's product manual, and using only the manufacturer-recommended UV lamps, can reduce the risk of electrical fires in sunlamp products. The manufacturer's product manual can be obtained by contacting the manufacturer or distributor.

FDA Actions

The FDA will keep the public informed if significant new information becomes available. More information on tanning products can be found on the FDA's Tanning Products webpage.

Reporting Problems with Your Device

If you experience a problem with a tanning bed or booth, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form. Reporting forms may be downloaded at: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.

Questions?

If you need further clarification, please feel free to contact Rick Wendt, Operations Manager, Radiation Protection Services at 971-673-0505 or via email at: richard.a.wendt@dhsoha.state.or.us