DATE: February 24, 2025

TO: Tanning Equipment Retailers, Tanning Business Owners, and Regulatory Environmental Health Programs

FROM: Food and Lodging Unit, ND Department of Health and Human Services

SUBJECT: Replacement of Indoor Tanning Ultraviolet Lamps with Red Light Lamps in Tanning Beds and Booths is Prohibited

The North Dakota Department of Health and Human Services, Food and Lodging Unit (Department), has become aware that some resellers of tanning equipment and tanning business owners are removing the original ultraviolet (UV) emitting tanning lamps from tanning devices and replacing them with lamps that emit red light with the intent to operate the device as red light therapy (RLT).

<u>Ultraviolet tanning beds/booths/lamps</u> meet the FDA's definition of "device" and "electronic product" in sections 201(h) and 531 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Tanning lamps are subject to an electronic product performance standard and are generally exempt from 510(k) clearance or premarket approval from the FDA (21 CFR 878.4635, part 1010, and 1040.20). Red lights intended for uses such as the reversal of sun or UV damage to the skin, stimulating cellular activity, promoting healing, and other skin improvement claims are not 510(k)-exempt. Therefore, tanning devices being used for this intended purpose without clearance or premarket approval from the FDA would be adulterated and misbranded and may not be marketed for sale.

North Dakota Administrative Code (N.D.A.C.) § 33-42-01-05(2) states that a replacement lamp for a tanning unit shall be compatible with the original lamp as specified by the manufacturer of the unit or shall be substantially equivalent to the manufacturer's original lamp type. "Substantially equivalent" means within 10 percent of the UV-B emission of the original lamp and meeting the performance requirements of the FDA per 21 CFR 1040.20(c)(1). N.D.A.C. § 33-42-01-06 further details the duties of the operator to include the use of only tanning equipment manufactured and certified to comply with 21 CFR part 1040, section 1040.20, "sunlamp products and ultraviolet lamps intended for use in sunlamp products", in tanning facilities.

The use of red light lamps in tanning devices manufactured for ultraviolet tanning is prohibited in tanning facilities operating in North Dakota. For questions about tanning facilities and the applicable regulatory requirements, please contact the Food and Lodging Unit at 701.328.1291, email <a href="mailto:foodandlodging@nd.gov">foodandlodging@nd.gov</a>, or contact your local health unit.