



March 19, 2010

RE: Docket **FDA-2009-N-0606**

Submitted via www.regulations.gov

Dear Members of the FDA General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee:

On behalf of the Melanoma Research Alliance (MRA), thank you for the opportunity to comment on the need for increased regulation of tanning lamps. MRA is a public charity that accelerates the pace of scientific discovery and its translation in order to eliminate suffering and death due to melanoma. Since inception in 2007, MRA has awarded almost \$16 million to 37 innovative research programs worldwide aiming to improve melanoma prevention, diagnosis, and treatment.

Melanoma is one of the most common cancers in the U.S., and the incidence is rising. Melanoma accounts for only four percent of all dermatologic cancers, but 80 percent of skin cancer-related deaths because of its ability to spread widely to other parts of the body. Very few treatment options exist once the cancer has spread, and patients with disseminated Stage IV melanoma have a median life expectancy of less than one year. In 2009, almost 70,000 Americans were diagnosed with melanoma and nearly 9,000 died of the disease.

Sadly, many melanomas could be prevented simply by reducing exposure to UV radiation, the leading environmental factor in the development of skin cancer. Evidence linking the use of UV tanning devices to melanoma and squamous cell carcinoma skin cancers has been broadly published. The recent classification of tanning beds as cancer-causing agents by the world's leading scientific authority on carcinogens – the International Agency for Research on Cancer (IARC) – sounded the alarm (IARC Working Group, Special Report: Policy; A review of human carcinogens-Part D: radiation, *Lancet Oncology*, 2009). The classification of UV radiation and tanning devices as “carcinogenic to humans” puts them in the same category (Group 1) as cigarettes, mustard gas, and plutonium, which are also scientifically proven to cause cancer.

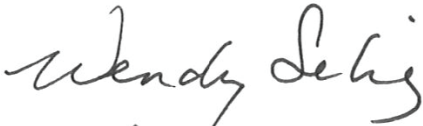
The IARC Working Group on artificial UV light and skin cancer published a meta-analysis which reviewed numerous published studies on this topic and clearly established a 75% increased risk of melanoma in indoor tanning bed use before age 35, and a 225% increased risk of squamous cell carcinoma associated with indoor tanning (IARC Working Group on artificial UV light and skin cancer, *The association of use of sunbeds with cutaneous malignant melanoma and other skin cancers: A systematic review*, *International Journal of Cancer*, 2006). On an average day in the U.S., more than 1 million people use tanning salons, and nearly 70% are girls and women, primarily aged 16 to 29 years (American Academy of Dermatology, www.aad.org/gov/congressional/_doc/FACTSABOUTINDOORTANNINGSKINCANCER.pdf).

The tanning industry has argued that cutaneous production of Vitamin D outweighs the risks of UV exposure to skin. This argument is deeply flawed because oral supplements of vitamin D produce identical (and more predictable) vitamin D supplementation, without carcinogenic risk. Attempts by the tanning industry to make these erroneous medical claims have led to a lawsuit by the State of Texas against Darque Tan.

The public is becoming increasingly aware of the dangers of UV exposure and the risks for melanoma, but much more must be done. The FDA can play a crucial role in this process by elevating its regulatory classification of tanning devices. The current classification (Class I) is unacceptable because it suggests that tanning beds are as innocuous as band-aids and tongue depressors. Enhanced regulation by the FDA to protect the public from the known health danger of UV exposure could prevent many from receiving a diagnosis of skin cancer in the future and help reduce suffering and save lives from melanoma.

Thank you for the opportunity to submit our comments. We commend FDA for beginning this important review to protect the public's health.

Sincerely,

A handwritten signature in cursive script that reads "Wendy Selig". The signature is written in black ink and is positioned above the typed name and title.

Wendy K.D. Selig,
MRA President and Chief Executive Officer