Sunless Tanners & Bronzers

A number of cosmetic products are marketed for consumers to achieve a tanned appearance without having to go out in the sun or use artificial sources of ultraviolet radiation. FDA has received questions about some of these products. The following information is provided in response to these questions.

What are "sunless tanners"?

Neither the laws nor the regulations enforced by FDA define the term "sunless tanner." It typically refers to products that provide a tanned appearance without exposure to the sun or other sources of ultraviolet radiation. One commonly used ingredient in these products is dihydroxyacetone (DHA), a color additive that darkens the skin by reacting with amino acids in the skin's surface.

What are "bronzers"?

Like the term "sunless tanner," "bronzer" is not defined in either the laws or the regulations enforced by FDA. It is often used to describe a variety of products intended to achieve a temporary tanned appearance. For example, among the products marketed as bronzers are tinted moisturizers and brush-on powders. These produce a temporary effect, similar to other types of makeup, and wash off over time. Some products are marketed with other ingredients in addition to DHA in order to provide a tanned appearance.

What does the law say about color additives, and DHA in particular?

The **Federal Food, Drug, and Cosmetic Act (/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/ucm2005640.htm)** (FD&C Act), Section 721 authorizes the regulation of color additives (other than coal-tar hair dyes), including their uses and restrictions. These regulations are found in **Title 21, Code of Federal Regulations (21 CFR), beginning at Part 70 (http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=f277364505462b302fc7e851be737ee5&tpl=/ecfrbrowse/Title21/21cfr70_main_02.tpl)**. If a color additive is not permitted by regulation or is used in a way that does not comply with the specific regulation(s) authorizing its use, it is considered unsafe under the law. Such misuse of color additives causes a cosmetic to be adulterated.

DHA is listed in the regulations as a color additive for use in imparting color to the human body. However, its use in cosmetics--including sunless "tanning" products--is restricted to external application (**21 CFR 73.2150 (http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=f277364505462b302fc7e851be737ee5&rgn=div8&view=text&node=21:1.0.1.1.27.3.31.8&idno=21)**). According to the CFR, "externally applied" cosmetics are those "applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane" (**21 CFR 70.3 (http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=f277364505462b302fc7e851be737ee5&rgn=div8&view=text&node=21:1.0.1.1.25.1.31.1&idno=21)**v). The industry has not provided safety data to FDA in order for the agency to consider approving it for use on these exposure routes, including "misting" from tanning booths.

In addition, no color additive may be used in cosmetics intended for use in the area of the eye unless the color additive is permitted specifically for such use (**21 CFR 70.5 (http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=f277364505462b302fc7e851be737ee5&rgn=div8&view=text&node=21:1.0.1.1.25.1.31.2&idno=21)**a) DHA is not permitted for use in the area of the eye. The CFR defines "area of the eye" as follows:

"the area enclosed within the circumference of the supra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge." (21 CFR 70.3s)

As with the lips and other areas covered by mucous membrane, the industry has not provided safety data to FDA in order for the agency to consider approving it for use in the area of the eye.

The regulations listing DHA as a color additive also require it to meet tight specifications, with strict limitations on impurities. For example, volatile matter must not exceed 0.5 percent when measured at 34.6 degrees centigrade for three hours at a pressure of not more than 30 mm. mercury. (Please note that the reference to "millimeters of mercury" is a measure of atmospheric pressure, not an indication that DHA contains mercury.) Certain minerals are restricted to miniscule amounts, measured in parts per million (21 CFR 73.1150 and 73.2150).

What does this mean for DHA spray "tanning" booths?

As noted above, the use of DHA in "tanning" booths as an all-over spray has not been approved by the FDA, since safety data to support this use has not been submitted to the Agency for review and evaluation, When using DHA-containing products as an all-over spray or mist in a commercial spray "tanning" booth, it may be difficult to avoid exposure in a manner for which DHA is not approved, including the area of the eyes, lips, or mucous membrane, or even internally.

Consequently, FDA advises asking the following questions when considering commercial facilities where DHA is applied by spraying or misting:

- Are consumers protected from exposure in the entire area of the eyes, in addition to the eyes themselves?
- Are consumers protected from exposure on the lips and all parts of the body covered by mucous membrane?
- Are consumers protected from internal exposure caused by inhaling or ingesting the product?

If the answer to any of these questions is "no," the consumer is not protected from the unapproved use of this color additive. Consumers should request measures to protect their eyes and mucous membranes and prevent inhalation.

What about sunless tanning products sold in retail stores, such as creams and lotions?

DHA is approved for external application to the human body, which is the way these products are intended to be used. Consumers can easily avoid inhaling them or applying them to the area of the eye or mucous membrane.

Who is responsible for the safety of spray tanning booths?

The FD&C Act does not authorize FDA to approve cosmetic products or ingredients, with the exception of color additives that are not coal-tar hair dyes. Firms and individuals who market cosmetics are responsible for assuring that the products they market are safe when used under labeled or customary conditions of use and properly labeled. FDA can take action against firms and individuals who violate the law. The practice of administering such products by professionals, such as in salons, is generally the responsibility of local and state health authorities.

For more information about the regulation of cosmetic products and ingredients, see **FDA Authority Over Cosmetics (/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm)**.

Do sunless tanners and bronzers provide protection from the sun?

Sunless tanners and bronzers may or may not provide protection from the sun. Only those sunless tanners that contain sunscreen ingredients and are labeled with sun protection factor ("SPF") numbers may provide protection. Consumers are advised to read the labeling carefully to determine whether or not these products provide protection from the sun.

All suntanning preparations that do not contain sunscreen ingredients are required to carry the following warning statement on the label:

"Warning--This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn." (21 CFR 740.19)

Sunscreens are regulated as **over-the-counter drugs (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm093452.htm)** unless they are used in the product for reasons other than protecting the consumer from the sun, such as protecting the product itself from fading. Cosmetic products that are marketed with sun-protection claims, such as makeup labeled with SPF numbers, are regulated as both drugs and cosmetics. (See "**Is It a Cosmetic, a Drug, or Both (Or Is It Soap? (/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm)**")

Has FDA received reports of adverse reactions associated with sunless tanners?

FDA has received reports from consumers stating that they have experienced adverse events associated with sunless tanning, including rashes and, primarily in the case of spray tanning booths, coughing, dizziness, and fainting. It is uncertain what, if any, ingredient or combination of ingredients in the sunless tanning products might have caused these adverse events, whether an individual's allergic reaction might have played a part, or whether factors unrelated to the sunless tanning products may have been involved, such as pre-existing medical conditions.

Under the authority of the Fair Packaging and Labeling Act (FPLA), FDA requires ingredient declarations on cosmetics sold on a retail basis to consumers. In this way, consumers can know what ingredients are contained in the products they purchase and avoid ingredients to which they may be sensitive. However, the FPLA does not apply to products used exclusively by professionals, such as those used in spray tanning booths.

How can I report an adverse reaction to sunless tanners or other cosmetics?

Consumers and healthcare providers can report adverse reactions from cosmetic products, including sunless tanners, to the nearest FDA office, listed in the blue section of the telephone book. Consumers and healthcare providers can report adverse reactions from cosmetic products, including sunless tanners, using the contact information in **Bad Reaction to Cosmetics? Tell FDA (/Cosmetics/ComplianceEnforcement/AdverseEventReporting/ucm388817.htm)**.

With the following updated contact information:

You can report a problem with a cosmetic to FDA in either of these ways:

1. Contact **MedWatch (/Safety/MedWatch/default.htm)**, FDA's problem-reporting program, on the Web or at 1-800-332-1088, or file a MedWatch voluntary **report online (https://www.accessdata.fda.gov/scripts/medwatch/)**
2. Contact the **consumer complaint coordinator (/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm)** in your area.

To learn more, see **Adverse Event Reporting: How to Report a Cosmetic-related Problem to FDA (/Cosmetics/ComplianceEnforcement/AdverseEventReporting/default.htm)**.