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Sunscreen: Yesterday, Today, Tomorrow

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One thing is clear—consumers and many skin care professionals do not know as much about safe sun as they should. Our profession needs to embrace educating clients on sunscreens, and safe sun needs to become more paramount. There are a myriad of popular misconceptions, even about SPF ratings. It is amazing to think that many consumers and skin care professionals thought an SPF rating of 15 meant that one could safely stay in the sun for 15 hours. SPF is not related to time of solar exposure, but rather the amount of solar exposure which varies based on the time of day. One hour in the sun at 9 AM may equate to 15 minutes at 1 PM.

The goal of this article is to provide a primer on sunscreen rules and regulations, what is allowed and what is not coupled with the tortuous and still pending litany of the U.S. Food and Drug Administration (FDA) regulations governing sunscreens, which are classified as over the counter (OTC) drugs. Our personal safety and the environmental health of the planet are greatly impacted by sun care as is the spiraling cost of health care for increased skin cancer, which is becoming an expensive aspect of health care.

Sunscreen Beginnings

The history of sunscreens in the United States has been anything but a simple journey. The quest actually had its origins in corrupt snake oil salesmen who promised that their secret potion could cure or grow any malady known to mankind. Their unscrupulous practices led to the formation of the U.S. Food and Drug Act in 1906,[1] which prohibited

the selling of misbranded and adulterated food and drugs. The organization morphed into the Bureau of Chemistry to regulate and prosecute companies and individuals that ran afoul of emerging regulations designed to protect the public.

Spurred by a tragic series of deaths in 1937 caused by the use of a poisonous solvent diethylene glycol,[2] Congress aggressively decided that they knew how best to protect the public and passed the Federal, Drug and Cosmetic Act (FDCA) in 1938. Simply put, anything intended to affect the form and structure of the body including cosmetics was now to be regulated by the U.S. federal government. This included cosmetics and products intended for the beautifying, cleansing or altering the appearance of the body.[3] Sunscreens were, and still are, classified as drugs, subject to the review of the FDA. Looking forward, the fact that no new sunscreen ingredients have been introduced in

the United States in over a decade, despite worldwide acceptance of a new, safe family of improved sunscreen formulations and ingredients available worldwide, had its origins in these government regulations, some say to the determent of our country.

The earliest modern sunscreens were designed around the mid-1930s to prevent burns but encourage the skin to tan. Scientist and mountain climber Eugene Schueller was the first person to come up with the idea of modern sunscreens in 1936-1938. His goal was to protect the skin without stopping a tan. Schueller went on to form L'Oreal, which is considered by many to be the progenerator of sunscreens. The early commercially available cream, Glacier Cream, with an SPF equivalent of 2, was brought to market by Swiss chemist
Franz Greiter. This eventually led to the creation of Coppertone.4 Shortly after, the U.S. military produced a product called Red Vet Pet, 5 short for red veterinary petrolatum, to prevent soldiers who were stationed in the pacific war zone from burning their skin. It was thick, sticky and really did not work.[5]

The Allure of Tanning

The next two decades brought forth a myriad of ad campaigns that encouraged tanning such as Ban de Soleil SPF 4 and Coppertone's "don't be a paleface," prompting the look equating beauty and fashion with being tan while smoking cigarettes. No one understood or grasped the concept that a tan is a burn and the practicing safe sun was vital to one's health. The next onslaught in the quest for beauty and fashion was surrounding one's face with reflectors and baby oil mixed with iodine to get the hot look. No one ever conceived the notion that a tan is actually a scar that damages the skin and can cause cancer.

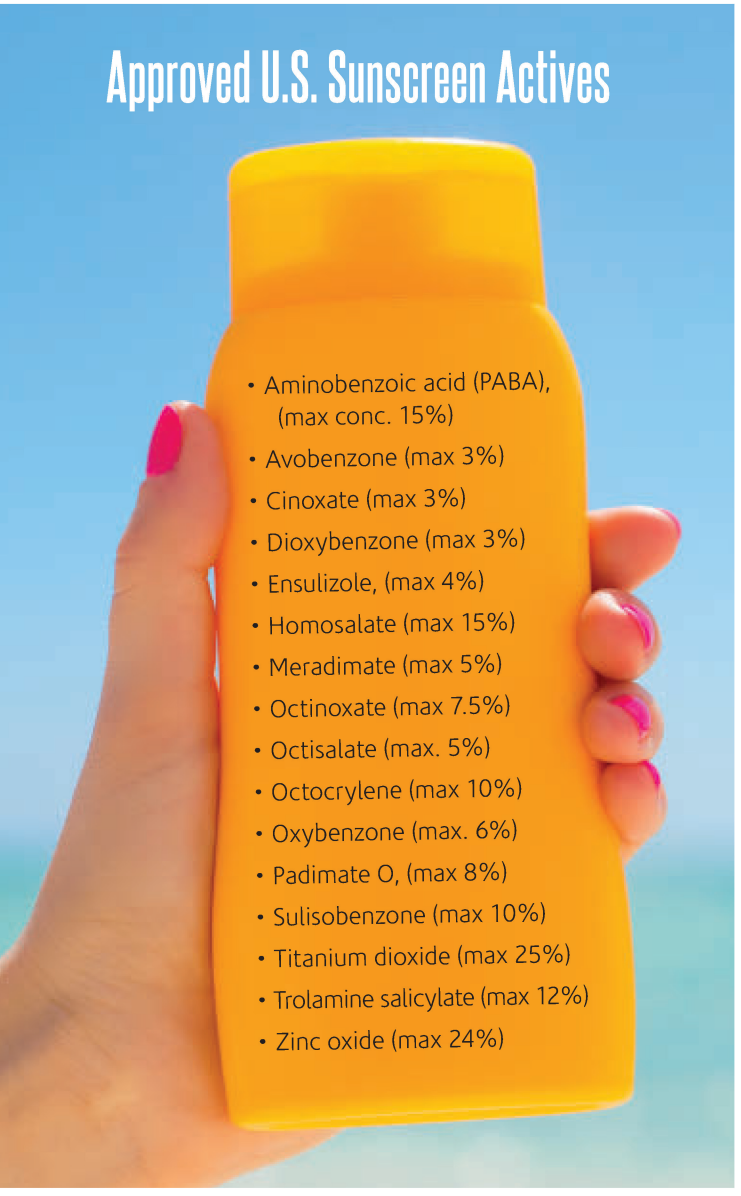
Emerging FDA Regulations

Skipping forward to 1978, the FDA published its first proposed rules regarding the designation of sunscreens as an OTC to be regulated, and it promulgated a list of 21 ingredients that would be considered generally recognized as safe and effective (GRASE).[6] Very little has changed since then. These regulations did establish two classes of ingredients: physical sunscreens that reflect and block the sun's rays; and chemical sunscreens that safely absorb UV radiation. This led to the creation of a standard SPF factor as a practical way to alert consumers to the effectiveness of a product.

SPF can be misleading and even dangerous. SPF (introduced in 1974) is a measure of the fraction of sunburn-producing UV rays that reach the skin. For example, a rating of 15 means 1/15 of the burning rays will reach the skin if a thick application is applied

evenly (two milligrams per centimeter squared). Most sunscreens will not remain effective for more than 90 minutes and must be reapplied.[7]

Many people think the higher the SPF rating, the more protection you get. This is only marginally true. The difference between an SPF of 100 and 50 is only 1% more protection and with the recommended SPF of 30 you obtain 96.7%.[8] Sun protection is more about applying adequate amounts of product and reapplying every 90 minutes rather than just a rating. In fact, there is a growing body of evidence that demonstrates people who use higher SPF rated products stay out in the sun longer, feel very protected and don't reapply and hence actually end up with greater incidences of skin cancers.[8, 9] The authors proposed that higher rated sunscreens may encourage prolonged sun exposure because of a delayed sun burn occurrence, a false sense of protection and a less frequent reapplication in adequate quantity.[9] There is compelling data that shows a strong relationship between duration of recreational sun exposure and skin cancer. Most individuals do not apply adequate quantities of sunscreens to gain protection.



Can Sunscreens Protect You?

There is evidence that sunscreens can prevent melanoma and squamous cell carcinoma but are not always effective in preventing basal cell carcinoma.[10] It is important to note that the average number of skin cancers is increasing at alarming rates, doubling in the last decade. The National Cancer Institute reports only 1/3 of the population take all steps needed to reduce the potential of developing skin cancer.[11]

Consumer research and the American Academy of Dermatology Association proved you cannot trust a brand's SPF label.[12] Consumer Reports tested 74 sunscreens and showed that 24 had actual protection of less than half of their advertised strength. No longer could the consumer trust the label.

Clinical studies show most sunscreens don't have the right ingredients, and natural sunscreens test far worse than products that contain both physical and chemical blockers. Many advise to look for formulations that include avobenzone, octissalate, octocrylene and homosalte coupled with physical blockers like titanium dioxide, zinc oxide or both. Broad spectrum products protect against the sun's harmful UVA and UVB rays.

Misconceptions exist about a sunscreen's duration against time in water. There are only water-resistant sunscreens that require reapplication after going into water. The government has to intervene to force manufactures to adjust their false waterproof claims.

Sunscreens and the Environment

There is an ever increasing body of evidence that certain sunscreens can damage the environment by increasing the production of hydrogen peroxide, which damages phytoplankton.[13] Nanoparticles of titanium dioxide can accumulate in coastal waters and be

harmfully ingested by marine animals and damage coral.[14] Starting in 2021, some states, like Hawaii, will ban the use of certain sunscreens due to their causing environmental damage.[15] Make sure the sunscreen you offer is compliant.

The EWG issued a report (The trouble with ingredients in sunscreens/EWG's 2018 Guide to Sunscreens) warning that our current formulations may disrupt hormone systems, could penetrate the skin and enter living tissues in a harmful manner, effect reproductive systems and foster other toxicity concerns. Many scientists have still not yet reached these same conclusions.

FDA Rule Making: Ingredients and Claims

FDA never finalized the 1999 OTC sunscreen final rule. In 2011, the FDA published a draft of their enforcement policy guide acknowledging that it did not intend to take enforcement actions against certain sunscreen products, provided they met several conditions. Any sunscreen product that was not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) for a generic of an already approved drug could be marketed as long as it met certain requirements established by both the 1999 monograph and more recent guidelines.

Today, FDA allows for the marketing of OTC sunscreen products that:

1. Have only the active ingredients (or combinations of active ingredients) permitted in **Approved U.S. Sunscreen Actives**;
2. Have active ingredients that each contribute at least SPF 2 to the finished product
3. Have a combination of the actives listed except for avobenzone with aminobenzoic acid, ensulizole, meradimate, padimate O, titanium dioxide, or zinc oxide;
4. Do not make non-permitted claims (see below);
3. That comply with the requirements for registration, recognition as GRASE, testing and labeling, adverse event reporting and provisions of the FD&C Act addressing adulteration;
4. That are marketed in an appropriate dosage form (i.e., oil, lotion, cream, gel, butter, paste, ointment, stick or spray); and
5. That may contain EPA-approved insect repellents.

Note that the following were disallowed:

1. Sunscreen products that pose a potential health hazard to the consumer;

Sunscreens that use natural and chemical blockers protect better.

2. Products containing, as an active ingredient, active ingredients or combinations not included in the list;
3. Products containing an insect repellent ingredient not registered by EPA;
4. Products in specific dosage form (wipes, towelettes, powders, body washes or shampoos);
5. Products making claims in labeling or promotional materials suggesting or implying that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging;
6. Products making claims such as "sunblock," "sweat proof" and "waterproof;"
7. Products claiming to instantly or immediately protect upon application; and
8. Products making claims to protect all day or protect for an extended period of time that are inconsistent with FDA-established directions for application in 21 C.F.R. § 201.327.

The Sunscreen Innovation Act

In 2014, Congress passed the Sunscreen Innovation Act (SIA), which established an expedited process through which FDA could review and approve OTC sunscreen products that have a history of safe and efficacious use in other countries. Among other requirements, the SIA also set a five-year statutory deadline for FDA to finalize regulations concerning these sunscreen ingredients. In 2014, the FDA began reviewing eight sunscreen active ingredients with a history of availability in other countries, namely bemotrizinol, bisoctrizole, drometrizole trisiloxane, octyl triazone, amiloxate, diethylhexyl butamidotriazone, ecamsule and enzacamene.[16]

In each case, FDA determined that more data was needed to characterize the safety and effectiveness of the ingredients. None of the additional data has been submitted by active ingredient sponsors as of 2018. It is vital to note most every country in the world can take advantage of a new generation of sunscreen ingredients, but not the United States. It is too long for those in the United States not to have the benefit of the next generation of sun protection formulations.

In 2016, the FDA published guidance documents for the industry describing the data needed to determine whether a sunscreen active ingredient is GRASE for use in OTC sunscreens under the SIA, guidance for skin safety studies and any providing past adverse reaction data and made recommendations for studies showing the extent and effects of the absorption of sunscreen active ingredients on the body.

The difference between an SPF 100 and an SPF 50 is only 1% more protection.

Looking Forward

FDA has recently stated that they are working on the mandate of SIA; however, we have not seen any real action. As the statutory deadline for the SIA approaches (November of 2019), we are sure to hear more from the FDA on the topic of sunscreen approval. The times are changing, but not fast enough to foster safe sun.

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