

US CONGRESS TO POTUS: IT DOESN'T HAVE TO BE THIS WAY!

IN A WORLD of inadequate sun care options, who decides which sunscreen products are available to you? In the US, the Food and Drug Administration seems to have absolute authority over the approval process that results in sunscreen products on store shelves. Even though any delay is dangerous and damaging to the public, changes in formulations and new products recommended by scientists and corporations have been rejected and stalled in bureaucracy.

This frustrating process is being resisted. For example, 54 members of Congress have asked President Barack Obama for help in implementing the bipartisan bill passed last year. A letter was circulated by Representatives Ed Whitfield and Debbie Dingell dated July 20, 2015 and addressed to President Barack Obama.¹ The letter urges the President to ensure that the Administration's calls for urgency in skin cancer prevention are heeded at the FDA so that Americans have access to the latest skin cancer prevention technology as soon as possible.

Since "The Sunscreen Innovation Act"



Congressional members from both parties have called for the approval of new sunscreens.

was passed unanimously by both the House and the Senate in November 2014, and signed immediately by the President, no positive action by the FDA has been taken. In fact, the FDA recently announced that it would delay consideration of eight new sunscreen ingredients through the Time and Extent Application (TEA). These ingredients have been used all over the world, many of them for several years. The FDA has even failed to approve, under the TEA process, an over-the-counter (OTC) sunscreen ingredient (ecamsule) that it had already approved as safe and effective in 2006 under a New Drug Application (NDA)!

This cat and mouse game with the FDA has been going on for decades and with the TEA applications, specifically, for at least 13 years. On July 29, 2014, the US Surgeon General's "Call to Action to Prevent Skin Cancer" concluded, "We must act with urgency to stop the ever-increasing incidence of skin cancers in the United States."² The Centers for Disease Control (CDC) have similarly called for an increased focus on skin cancer

prevention.³ Nearly 5 million Americans are treated for skin cancer every year at a staggering estimated cost of \$8.1 billion to US taxpayers. That figure does not include the cost in human suffering for the families of the nearly 9,000 Americans who die every year from melanoma, more than one every hour of every day. The letter pleads with the President declaring, "It doesn't have to be this way!"

Cat and Mouse

On July 9, 2015 in the New England Journal of Medicine, Joshua Sharfstein, MD of the FDA, wrote an article entitled "A Spotlight on Sunscreen Regulation."⁴ He repeated the same mantra emanating from the FDA for years, namely that sunscreen manufacturers should seek the NDA process as the only viable approach to approving new UV filters in the US. He dismisses The Sunscreen Innovation Act signed by the President as an approach that does not fully consider the agency's framework for reviewing of sunscreens, resource needs and public health role. Yet, again, we hear from another FDA official



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that ultraviolet filter approval should be treated in the exact way new prescription drugs are approved in the US. Sharfstein proudly cites that the FDA generally moves faster than European regulatory agencies and approved 41 products in 2014 (none of them are ultraviolet filters). He cites that the “key to this fast pace is the fact that under US regulatory law, the agency tailors its approval decisions to the data at hand, receives extra resources (from user fees) for drug reviews, and if problems emerge after approval, has the ability to move quickly with a range of actions to protect the public.”⁴

The stubborn message from the FDA is clear. Basically nothing will persuade the Administration to proceed with the approval of new UV filters in the US, not the Congress nor the President, nor even their own previously declared procedure of approving filters through the TEA process in less than a year.

Sunscreen manufacturers should abandon all current approaches in an attempt to approve UV filters and instead apply for an NDA. L'Oréal took this route with Ecamsule in 1999. Manufacturers are being asked, instead, to go through the tedious process that requires millions of dollars, possibly a half dozen years and includes all the long-term exposure data such as long-term skin irritation studies, carcinogenicity, teratogenicity, mutagenicity and developmental toxicology required for each UV filter. Many years after the initial application, millions of people will have suffered, productivity and wages will have been lost, billions in medical bills will have been spent and countless deaths from melanoma will have occurred unnecessarily. Upon approval, the manufacturer will be able to charge the US consumer as much as the pharmaceutical industry does with Lipitor, Crestor, Toprol or Avodart. But wait, there's more! That NDA is only valid for one cosmetic formulation. Yes, only one. If you change the percentage of any active, or include a new active or even change the vehicle from a lotion to a gel, you may possibly need an amended NDA to go to market. Good luck.

Is the FDA flexible enough to greet new

technologies and innovations? Its inability to respond to new developments damages our competitive standing in the market. In a recent article entitled “Biocompatible Material Contains Sunscreen from the Sea” written by researchers at the Royal Institute of Technology in Sweden and published in the American Chemical Society Applied Material Interfaces Journal in July 2015, new materials containing UV absorbing molecules found in algae and reef-fish mucus could serve as non-toxic, biocompatible sunscreens.⁵

The photostable materials could be used in cosmetics or as UV-protective coatings for outdoor furniture or clothing. The researchers have attached mycosporines that fish, algae and cyanobacteria produce, to chitosan polymers. Their new materials absorbed both UVA and UVB radiation effectively and were twice as active as octinoxate. Obviously, this new material will be approved in Europe decades ahead of its use in the US!

Consumer Lawsuits

The filtering of products through the FDA's approval process suggests that not even high quality sunscreens could ever make it to market. This, however, does not explain how ineffective products reach consumers. In July, a flurry of consumer complaints were posted concerning the safety and reliability of the so-called all-natural sunscreen (SPF 30) made by The Honest Company, which is owned by the actress Jessica Alba. The product is blamed for a number of severe sunburns. The company had recently reduced the zinc oxide active from 20% down to 9.3%. The Honest Company's response was that the product was tested and approved for SPF 30 by a third party testing company.

In another development, Consumer Reports tested a number of products on the market and found that about a third of the sunscreens tested did not meet their SPF claims!

In my February 2015 column, I wrote about a legal case, *Gisvold vs. Merck*. In another similar case, on June 9, 2015, in *Eckler and Engel vs. Neutrogena Corp.*, the two plaintiffs brought slightly different claims

that sunscreen labeling was misleading. The California Appellate court on grounds of preemption shot down those claims but the issues are still pertinent. Engel and Eckler focused on the terms “sunblock,” “waterproof” and “sweat proof,” which the FDA prohibited in a regulation published on June 17, 2011. The compliance date, however, was set at December 17, 2012. They claimed that the defendant should have gotten rid of those terms even before the FDA's compliance date. The plaintiffs also raised the issue of the claims of SPF with values greater than 50 and said that sunscreen labels were deceptive advertising and unlawful business practices under California's Unfair Competition law. The Supreme Court concluded that Engel's claims were entirely preempted since the FDA Modernization Act of 1997 included a provision expressly preempting state law requirements regarding nonprescription drugs, including sunscreen products.⁶

Space limitation makes it impossible to include all the discussion needed to resolve these issues. This month, two important conferences relevant to our field will be held. The first is Happi's Anti-Aging Conference & Tabletop Exhibition on September 10 & 11 in New Brunswick, NJ, and the second will be held in Orlando on September 17-19 when the Florida Sunscreen Symposium takes place. A traditional roundtable discussion will be held in both conferences with representatives from both the industry and the FDA present. I guarantee you a lively and interesting discussion on all issues related to sunscreens. ●

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