

# THE ARCHAIC TEA PROCESS REVISITED

**T**HE US has fallen behind in the adoption of sun care ingredients that are actively in use in other countries. What are the reasons for this lag? Recently, I was invited to participate in a coalition that endeavors to improve the regulatory pathway for US sun care ingredients and products. This coalition is called the Public Access to Sunscreens (PASS). It is a multi-stakeholder coalition of health organizations, sun care ingredients suppliers, brand owners, NGOs, MD dermatologists Henry Lim, Harry Fallick, Steven Wang, Warwick Morison and other scientists including Joe Stanfield and myself (see *HAPPI, April, 2013, p. 52*). This group is quite active and has met at least once weekly since the beginning of this year. The group is focused on a singular issue and has already had meetings with the FDA and multiple information sessions with congressmen, senators and their staffers.<sup>1</sup>

The issue at hand is the Time and Extent Application (TEA) of eight European ingredients that are currently being reviewed by the FDA. None have been approved for use in the US. These ingredients are shown in Table 1.

**TABLE 1: EUROPEAN INGREDIENTS UNDER FDA REVIEW**

Ingredient	TEA Date	Docket
Amiloxate	8/14/2002	FDA-2003-N-0196
Enzacamene	8/21/2002	FDA-2003-N-0196
Octyl Triazone	8/21/2002	FDA-2003-N-0196
Bemotrizinol	4/11/2005	FDA-2005-N-0453
Bisotrizole	4/11/2005	FDA-2005-N-0453
Isotrizinol	9/16/2005	FDA-2006-O-0314
Ecamsule	9/18/2007	FDA-2008-N-0474
Drometrizole Trisiloxane	1/21/2009	FDA-2003-N-0196

As can be seen from the table above, three of those ingredients date back to 2002. The Final Rule stated that the FDA “will strive to complete TEA application in 90-180 days”! I have long held the view that the FDA is reluctant to finalize the TEA sunscreen filter ingredients for use in the US due to the safety issues in connection with new ingredients and those of the currently approved ultraviolet filters. Forefront on their minds, are issues dealing with penetration of UV filters into the skin and the potential safety considerations. These issues affect the safety of the currently approved Category I ingredients including oxybenzone, the other smaller molecules (in particular the salicylates and cinnamates), the photostability of avobenzone and also nanoparticle issues relating to zinc oxide and titanium dioxide. A final assessment on all of those issues have been promised but not yet addressed. These are Monograph issues.

as the primary culprit in this ongoing debate. It’s the entity that receives all the blame. The science, however, is evolving rapidly. New discoveries and information on topics such as testing, ingredients, products, sources of radiation, non-compliance and toxicity are surfacing daily.

The negative chatter on the internet from bloggers, dermatologists, private citizens, environmental organizations and others is relentless. The PASS Coalition advocates working with the FDA to ensure that it has the resources needed to complete a timely review of the TEA ingredients. The coalition wishes to insure that the FDA has all the necessary tools to review vital new medical advancements and is proposing a “user fee” program. This model charges the TEA applicants a predetermined fee to support the FDA’s review process in exchange for a guaranteed predictable time frame response from the agency.

The coalition asserts<sup>2</sup> that if this program is implemented, it will benefit the American public because:

## Evolving Science

The FDA has been unfairly singled out



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Dr. Nadim Shaath is the president of Alpha Research & Development, Ltd. in White Plains, NY. He has over 30 years of experience as chairman of the chemistry department at SUNY-Purchase and the CEO of Kato Worldwide. Recently he formed a consulting company serving the cosmetic industry called ShaathMeadows Corporation (SMC) with laboratories in New York, New Jersey, Texas, Florida and Egypt.

- Consumers would gain more rapid access to the safest and most effective sunscreens.

- New active ingredients would receive a thorough review for effectiveness and safety within a predictable timeline.

- Costs to ensure an expeditious review by the FDA would be borne by industry—not the US taxpayer.

Complicating matters are citizen petitions like the one recently submitted by Dr. Robert Sayre, a top scientist in sunscreen testing.<sup>3</sup> His petition to the FDA on March 2013 requested the Commissioner of Food and Drugs specifically to amend approval for the sunscreen agents, listed in 21 CFR Part 352-Sunscreen Drug Products for Over-the-Counter Human Use, Subpart-B 352.10 Sunscreen active ingredients (58 FR 28195) and any additional regulations. Sayre's petition requests that the FDA formally withdraws approval of the anti-inflammatory sunscreen ingredients dioxybenzone, oxybenzone, trolamine salicylate, homosalate, and octisalate. He also requests that the Commissioner of Food and Drugs reassess 21 CFR Parts 201 and 310, Subpart VII. SPF Test Issues (Other than Test Parameter), D. anti-inflammatory ingredients and specifically amend 21 CFR Parts 201 and 310, Subpart VI. SPF Test Parameters to include sunscreen testing methodology to prescreen products that decrease the erythema response and falsely inflate SPF values determined in SPF testing. Sayre's claims emanate from the latest research on benzophenones and salicylates that have been identified in US patents as anti-inflammatory agents.<sup>4-6</sup>

He adds "suppression of UV-induced erythema by means other than attenuation of radiation clearly masks sunburn without preventing cellular/genomic damage."<sup>3</sup>

The FDA had dismissed this concern in 2011,<sup>7</sup> asserting that "it seems unlikely that anti-inflammatory ingredients will affect SPF values because their anti-erythemal effect is relatively short-lived compared to the 16-24 hour interval between UV exposure and erythema observation in the

SPF test." Sayre, however, points out that his study using an SPF 100 product clearly shows that at four hours all early sunscreen treated UV erythemal responses were eliminated.<sup>8</sup> He concluded that "clearly the sunscreen product altered not only both the early and the delayed erythemal responses but also longer term pigmentation responses."

With studies and claims such as those reported by Sayre and with others claiming important considerations impacting issues dealing with skin penetration of sunscreen ingredients,<sup>9,10</sup> irritation potential of UV filters, toxicity and endocrine disrupting potential of oxybenzone and other UV filters,<sup>11,12</sup> the FDA is reluctant to approve the eight TEA ingredients in question or comment on the updated safety and reliability of the currently approved UV filters.

### Call for an Expert Panel

We have clearly reached crisis stage and the solution does not lie with the FDA alone. It also rests with the Congress, the White House, consumer product companies, sunscreen ingredient suppliers, scientists, dermatologists and concerned citizens. To get it resolved satisfactorily an "Expert Panel" must be assembled, led by the FDA, and sanctioned by Congress and the White House, and involve the best scientists, experts and dermatologists that this country can provide. This Expert Panel would convene as it did in 1972 and issue a final recommendation on the safety and use of all applicable ultraviolet ingredients approved for use in the US.

### References

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**They may look the same from the outside, but US sun care formulas don't contain the latest active ingredients due to inaction by regulators.**



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12. European Commission on Endocrine Disruption (<http://ec.europa.eu/consumers/cosmetics>). •