FDA Citizen's Petition

Reclassification of the Organic Sunscreen Actives Currently Listed in Category III (Insufficient Data Available to Permit Final Classification) to Category II (Not GRASE)

OR

Incorporate Various Warning Statements to Allow Consumers to Understand the Health Risks Associated With Products Using Organic Sunscreen Actives

The undersigned submit this petition under CFR 10.30 of the Federal Food Drug and Cosmetic Act for which authority has been delegated to the Commissioner of Food and Drugs to request the Commissioner of Food and Drugs to enforce the reclassification of Category III Sunscreen Actives (insufficient data available to permit final classification) from the over-the-counter (OTC) sunscreen monograph to Category II (Not Generally Recognized As Safe & Effective for Human Use) "**OR**" incorporate appropriate warning statements allowing consumers to understand the health risks associated with their use.

A. Action Requested

On behalf of the signatories listed below it is requested that the Commissioner of the Food & Drug Administration reclassify all Category III Sunscreen Actives (insufficient data available to permit final classification) from the Over-the-Counter (OTC) sunscreen drug monograph to Category II (Not GRASE) "**OR**" incorporate appropriate warning statements (see below) allowing consumers to understand the health risks associated with their use. Especially since there is little to no evidence that sunscreens prevent skin cancer – especially the most-common form (basal cell carcinoma) and the most-deadly form (melanoma).

In a recent Viewpoint article[1], the Commissioner of the Food & Drug Administration states "The FDA must also maintain robust regulatory oversight to prevent unsafe or ineffective medical products from entering the market, or from being used in unsafe ways because of untruthful or misleading advertising or error-prone design." The published scientific literature relating to organic sunscreen actives demonstrates that these products are unsafe, ineffective and are being sold to consumers in a way that is untruthful or misleading by the sunscreen industry, some of the dermatological community and non-profit organizations that profit from sunscreen myths allowing consumers to believe that they are being protected from skin cancers based on confounded data.

The most serious and often irreversible risks not disclosed to consumers from these Category III actives are from fetal and early infant exposure with adolescence being the next crucial period. Until the FDA moves the 12 Category III actives to Category II and removes them entirely from the marketplace, the FDA should require products using these actives to carry a WARNING Label that says they pass through the skin to reach all tissues and cells in the human body, including the brain. Potential adverse events may occur and pregnant or nursing mothers and others who may be more at risk – young or adolescent children, and couples trying to conceive should avoid using sunscreens with these agents.

B. Statement of Grounds

Historically, the practice of allowing unsafe and/or untested drug actives/products into the marketplace prior to demonstrating safety and efficacy has led to several devastating consumer outcomes, many ending it death and/or deformity. These would include the drug actives Thalidomide (MW = 258.23 g/mol), Diethylstilbestrol (MW = 268.35 g/mol), Hexachlorophene (MW = 406.902 g/mol) and Triclosan (MW = 289.54 g/mol), Triclocarban (MW = 315.6 g/mol), to name only a few, that have been removed from the marketplace. Likewise, the current concerns relating to 14 organic sunscreen actives, recently removed from Category I status of Generally Recognized As Safe & Effective (GRASE) all have a molecule weight (MW) below 500 g/mol,

become readily bioavailable in the human body[2-7], and have hundreds of scientific papers in the published literature demonstrating numerous adverse reactions environmentally and to numerous life forms including humans.

The Food, Drug and Cosmetic Act of 1938 was signed into law technically to bring "cosmetics and medical devices under control, and it required that drugs be labeled with adequate directions for safe use. Moreover, it mandated pre-market approval of all new drugs, such that a manufacturer would have to prove to FDA that a drug is safe before it could be sold"[8]. Despite this history and law, industry appears to refuse to recognize and conduct the requested/required safety studies needed to comply/assure consumer safety. In addition to the law there are other tenet(s) that have been put in place to minimize human calamity. The "Precautionary Principle" has been used in environmental decision-making, regulating drugs and other consumer products in the United States as well as in some European countries[9]. This principle "rejects the claim that uncertainty justifies inaction, and its ambition is to empower policymakers to take anticipatory action even under scientific uncertainty"[10]. Similarly, physicians and medical students take a Hippocratic Oath and one of the promises within that oath is "primum non nocere," or "first, do no harm"[11]. There is a harmony and confluence between the law and these principles, however, the current situation relating to these Non-GRASE active ingredient(s) being used/sold in sunscreen and anti-aging products appears to once again be challenging the wisdom of the ages.

With that said, the undersigned wish to first, request that FDA move all of the organic sunscreen actives currently in question, as outlined in the February 26, 2019 Federal Register Proposed Ruling for Sunscreen Drug Products for Over-the-Counter Human Use, that are currently listed as Category III into Category II and that products containing such chemicals be phased out, within a reasonable timeframe, removing them and the potential harm from the US marketplace.

In the alternative, if attention is not paid to history, the following list of disclaimers and warning statements (in addition to any current regulatory statements required) should be mandated to allow consumers to be informed of the risks associated with the use of sunscreen and anti-aging products using Non-GRASE actives.

1) For any active ingredient used in a sunscreen or anti-aging product(s) identified in section "21 CFR 352.10", except for non-nano particle size actives "p" (Titanium dioxide) and "r" (Zinc oxide), alone or in combination with each other:

> *Warning: The safety of this product has not been determined[12]. The active ingredients used in this product can* pass through the skin to reach all tissues and cells in the human body, including the brain. Potential adverse events may occur and pregnant or nursing mothers and others who may be more at risk – young or adolescent children, and couples trying to conceive should avoid using sunscreens with these agents.
>
> *Warning: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies even if the FDA does not consider these products to be generally recognized as safe and effective (GRASE) for human use. FDA has not evaluated whether this product complies[12].*
>
> *Warning: This product contains one or more sunscreen actives known in the scientific literature to be Endocrine-disrupting chemicals (EDCs) that can interfere with normal male or female, adult or adolescent or infant, hormone activity increasing the risk of adverse health outcomes, including cancer, reproductive impairment, cognitive deficits, obesity and/or a reduction in normal growth milestones when compared to peers[13].*

Warning: Sun Protection Measures - Spending time in the sun increase your risk of skin cancer. This product has not been scientifically proven or tested to prevent skin cancers. To decrease this risk, limit time in the sun, especially from 10 AM – 2 PM, wear long-sleeved shirts, pants, hats and sunglasses. Ask a doctor before using on children of any age[14].

2) For products containing the active ingredient(s) "f" (Homosalate), "k" (Octyl salicylate; AKA Octisalate), or "q" (Trolamine salicylate) used in a sunscreen or anti-aging product(s) identified in section "21 CFR 352.10" alone or in combination with each other:

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness[12].

Allergy alert: Salicylates may cause a severe allergic reaction which may include: hives, facial swelling, shock, asthma(wheezing)[12].

Bleeding warning: This product contains an NSAID which may cause severe bleeding. The chance is higher if you: are age 60 or older, have had stomach ulcers or bleeding problems, take a blood thinning (anticoagulant) or steroid drug, take other drugs containing prescription or non-prescription NSAIDs (aspirin, ibuprofen, naproxen, or others), have 3 or more alcoholic drinks every day while using this product, take more or for a longer time than directed[12].

Pregnancy warning: If pregnant or breast-feeding, it is especially important not to use aspirin-like products during pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery[12].

3) For products containing the active ingredient(s) "i" (Octocrylene), "j" (Octyl methoxycinnamate; AKA Octinoxate) or "l" (Oxybenzone) used in a sunscreen or anti-aging product(s) identified in section "21 CFR 352.10" alone or in combination with each other:

Cancer and Reproductive warning: This product contains chemicals shown in the scientific literature to cause cancer[15], and/or increase the risk of spreading existing cancers and/or birth defects and/or other reproductive harm[16].

4) For products using the combination of active ingredients "b" (Avobenzone) and "j" (Octyl methoxycinnamate; AKA Octinoxate) used in a sunscreen or anti-aging product(s) identified in section "21 CFR 352.10":

Interaction warning: This product contains a combination of chemicals shown in the scientific literature to interact with each other rendering the product "less active" and/or in time "not active" increasing your risk of sunburn and/or skin cancer[17].

C. Environmental Impact

Although no formal environmental impact studies are being submitted with this petition, there have been multiple studies demonstrating that organic sunscreen actives adversely impact the coastlines and waterways throughout the United States harming marine life and coral[18].

Haereticus Environmental Laboratory (HEL) identifies the environmental impact that oxybenzone and octinoxate have on navigable water ways whose biological/ecological receptors and structures can be impacted by sunscreens as a result of waste-water discharge (point and non-point sources), swimmer contamination, and/or from aerosol spray discharges from boaters and inflatable and rigid personal crafts

(e.g., inflatable tubes, canoes, kayaks, paddle boards), all from the use of over-the-counter sunscreen SPF products. Contamination of these 851 bodies of waters in 21 States threaten subsistence fishers and USDA and National Marine Fisheries Service recognized fisheries in all the states listed below[19].

State of California (59 rivers and lakes); State of Colorado (9 rivers); State of Connecticut (36 rivers and lakes); State of Delaware 22 rivers and creeks); State of Hawaii (13 rivers and streams); State of Illinois (58 rivers and lakes); State of Indiana (37 rivers and lakes); State of Maine (30 rivers); State of Maryland (33 rivers and lakes); State of Massachusetts (35 rivers); State of Michigan (30 rivers); State of Montana (30 rivers); State of New Mexico (9 rivers); State of New York (37 rivers and lakes); State of Ohio (50 rivers and lakes); State of Oregon (124 rivers and lakes); State of Rhode Island (39 rivers);State of South Carolina (30 rivers); State of Virginia (40 rivers); State of Washington (100 rivers and lakes); State of Wisconsin (30 rivers).

Additionally, HEL also identifies 235 protected species at risk in the US: marine mammals (10); reptiles (8); birds (16); Bivalves (26); crustaceans (28); fish (140) and coral (7).

D. Economic Impact

No formal economic impact studies are being submitted with this petition; however, it should be noted that the financial cost associated with treating the impact to both human health (skin cancers) and the environment will be significant.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Joe D. Nardo (Signing for ALL signatories)

Name of petitioner	Joe DiNardo

(b) (6)

Signatories

Ted Bohlen Hawai'i Reef and Ocean Coalition	Lisa Bishop President Friends of Hanauma Bay
Cindi Punihaole Executive Director Kahalu'u Bay Education Center	Mendy Dant Executive Vice President Fair Wind Cruises

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