The FDA last month issued warning letters to companies the agency says illegally marketed dietary supplements that make unproven drug claims about protecting consumers from the harms of sun exposure. The action called attention to a largely overlooked and potentially dangerous segment of the dietary supplements market that appears to be capitalizing on growing consumer awareness of the dangers of UV exposure. Marketers evidently are claiming that various oral supplements can actually confer UV protection in the same manner as sunscreens. A few years ago, one company even attempted to market a beverage it said contained sunscreen ingredients.

But the FDA’s action also seems to have created confusion about other dermatology-related supplements and their potential application in patient care and has called into question the role of *Polypodium leucotomos* extract in patient care.

**WHAT THE FDA SAID**

FDA identified companies marketing four specific products: Advanced Skin Brightening Formula (GliSODin Skin Nutrients), Sunsafe Rx (Napa Valley Bioscience), Solaricare (Pharmacy Direct, Inc.), and Sunergetic (Sunergized LLC). In its warning letters, FDA noted that the manufacturers of these products made claims that had not been evaluated by the FDA and contained ingredients not generally recognized as safe and effective (GRASE). Furthermore, FDA said that to support such claims, the ingredients would need to be submitted for FDA review under the new drug application process.

Among examples of improper claims cited by FDA were comments such as this in a product review: “It’s basically an oral sunscreen…This would be especially useful for people who have had skin cancer, are at risk for skin cancer....”

Another company website contained the statement, “Solaricare only contains one ingredient [sic] Polypodium Leucotomos …. Used ... for treating skin disorders such as psoriasis, eczema, polymorphic light eruption and sunburn.”

“The concern to dermatologists and our patients should be that companies can get away with making false claims like this, similar to claims made by non-dermatologists who practice out of scope,” says Neal Bhatia, MD, FAAD. “In similar fashion, consumers are often fooled and believe these sorts of claims. The truth is that there is no such thing as an oral sunscreen.”

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Echoing the guidance of the American Academy of Dermatology and dermatologists nationwide, Dr. Bhatia stresses, “The only way to protect skin from the consequences of UV damage is to limit UV exposure during prime sun hours, routinely use FDA-approved sunscreen products, and optimize photoprotective clothing whenever possible.”

WHAT THE FDA DID NOT SAY

In a statement announcing the warning letters, the FDA did not indicate concerns about the ingredient Polypodium leucotomos (PL) generally, nor did it indicate that other brands were in violation of FDA guidance.

For its part, Ferndale Healthcare has noted that its Polypodium leucotomos extract-based product Heliocare was not part of the FDA warnings, nor does it make the claims that the cited products do.

“It is well established that Polypodium leucotomos extract (PLE) is not a form of chemoprevention, but there are demonstrated benefits on reducing UV-induced erythema when taken correctly,” Dr. Bhatia notes.

“Heliocare has significant science and responsible marketing behind their product,” observes Joel Schlessinger, MD, FAAD. “This hasn’t always been the case with this category, but we have to remember that no one product (including sunscreen) is entirely protective.”

In an article previously published in Practical Dermatology® magazine, Vivian Bucay, MD addressed the role for Heliocare as a skin support supplement. “Among its various mechanisms of action, Polypodium leucotomos extract is a potent antioxidant that quenches free radicals,” she wrote.

Dr. Bucay also noted that, “The agent, which has been reported in several peer-reviewed publications, inhibits production of matrix metalloproteinases (MMPs), such as collagenase and elastase. By reducing these, the agent allows the skin to maintain its architecture. The skin is thicker, more supple with better support.”

For a review in Journal of Drugs in Dermatology, Winkleman, et al. provided an overview of the data specific to Polypodium leucotomos available commercially in Heliocare, which they note has been evaluated in a variety of basic science and clinical studies. “Antioxidant effects of PLE are attributed to its ability to consume superoxide anions, lipid peroxides, and hydroxyl radicals... PLE is believed to inhibit the photodamage process, increasing the minimal erythema dose (MED), by maintaining extracellular matrix integrity and preventing damage to DNA repair enzymes.”

The authors further note that, “The anti-mutagenic effects of PLE are attributed to its ability to block ultraviolet (UV) radiation-induced COX-2 expression and promote p53 suppressor gene mutation.” Among the immunoregulatory effects PLE demonstrates in response to UV radiation are, “inhibited infiltration of neutrophils and mast cells, as well as reduced loss of antigen presenting Langerhans cells.”

It is worth noting that the use of PLE as part of a skincare regimen is just one method of reducing and repairing the effects of photodamage. Dr. Bhatia points out the Photolyases, a type of photo reactivation enzyme, have been garnering attention for their ability to repair DNA mutations and damage induced by UV radiation and their potential to influence the development of carcinogenesis. Although these enzymes have not been identified in humans, exogenous forms have been manufactured and are currently available in some topical formulations.

FDA EYES SUNSCREEN INNOVATION

In its statement about the warnings, FDA also announced new “steps to promote safe and effective innovations for sun protection.” The agency is encouraging industry research of additional sunscreen ingredients. FDA also issued another new draft guidance for industry regarding Maximal Usage Trials (MUST) for topically-applied active ingredients being evaluated for inclusion in an OTC monograph, including the OTC monograph for sunscreens.

Meanwhile, dermatologists will likely find themselves continuing to provide needed guidance to patients about sunscreens and antioxidant supplements. Dr. Schlessinger says he will continue to recommend Heliocare to his patients as part of a comprehensive skin protection and skin care regimen.

“Heliocare is my ‘go to’ product for patients with photosensitivity, lupus, and polymorphous light eruption, but it isn’t in a vacuum. We also recommend sunscreen and other treatments, depending on the level of sensitivity,” Dr. Schlessinger says. “Responsibly used, this can provide a huge benefit to so many patients and luckily, Heliocare has always been honest about what their product can and can’t do, so they weren’t involved in this shakeout.”