

OVER-THE-COUNTER (OTC) MONOGRAPH REFORM

CONGRESS is currently debating how to amend the Federal Food, Drug and Cosmetic Act to clarify the regulatory framework with respect to certain non-prescription drugs that are marketed without an approved new drug application. The proposed bill will be known as: "Over-the-Counter Monograph Safety, Innovation and Reform Act of 2017." As you know, sunscreens in the US are regulated as OTC drugs, and all the ultraviolet filters allowed for use have been approved through the so-called "monograph ingredients process." The only exceptions are avobenzone and ecamsule.

The FDA, the PASS Coalition (Public Access to Sunscreens) and others in the cosmetics industry have been actively engaging in meetings with members of Congress and other legislators while pleading their case for more suitable final sunscreen regulations in the US.

The PASS Coalition met with the FDA earlier this summer to review new and previously submitted pending sunscreen ingredients applications (the so-called TEA ingredients). This was followed up



Some Californians didn't have the brightest ideas to protect themselves during the recent solar eclipse.

by a letter from the PASS Coalition in July. Among the points of agreement that were reached with the FDA, the following items were included:

- Regulatory pathways must be flexible enough to accommodate sunscreen ingredients.
- Pending sunscreen ingredients should be considered under the Sunscreen Innovation Act (SIA) and any new products will be considered under the newly reformed OTC pathway.
- The specific testing and absorption requirements described in the FDA's November, 2016 guidance document entitled "Nonprescription Sunscreen Drug Products — Safety and Effectiveness Data" remain a recommendation, and the agency will be flexible in considering alternative testing regimes for sponsors in order to meet the agency's standard for products generally recognized as safe and effective. FDA's testing standards should be periodically reviewed and assessed.
- It has been recognized that the New Drug Application (NDA) is difficult for sunscreen ingredients and that sponsors of sunscreen ingredients should have alternate pathways to establish safety and efficacy.

The Director of the Center for Drug Evaluation and Research (CDER), Dr.

Janet Woodcock, responded promptly and stated that the FDA concurs, in principle, to our summary but added that it was important to add context to some of the major points:

- As to specific testing and absorption requirements, the FDA remains flexible in considering validated alternative testing procedures in support of a determination of general recognition of safety and effectiveness.

- Although the New Drug Application (NDA) process may be viewed as difficult, there have been sunscreen products approved under NDAs. This includes products containing ecamsule, one of the proposed sunscreen ingredients addressed by the Sunscreen Innovation Act; thus, some sunscreen products with ecamsule can currently be marketed in this country. The monograph process does not lessen data standards to establish the safety and efficacy of any sunscreen ingredient and the FDA has used flexibility in reviewing ingredients. The monograph process, however, clearly will allow more flexibility in formulating individual sunscreen products.

The FDA held three meetings in Congress the first week of August and followed it up with an Aug. 23 webinar



Nadim Shaath
*Alpha Research
& Development Ltd*
Email: alphamd@aol.com

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 and Nickstadt-Moeller. He has just published his new manuscript entitled: "Healing Civilizations: The Search for Therapeutic Essential Oils and Nutrients" Cameron Books, Petaluma, CA.

that focused mainly on “user-fees” but had some important information as well. The webinar was conducted by Dr. Sharon Mahoney, the deputy director of CDER’s Division of Non-Prescription Drug Products, who briefly reviewed the potential reforms that Congress is planning to undertake with the monograph process.

The “monograph” process was established in 1972 by regulation after a 1962 Congressional directive required the FDA to review the safety and effectiveness of all marketed drugs. The monograph was a means to address the safety and effectiveness of hundreds of thousands of existing OTC products without requiring each to have a separate New Drug Application (NDA). The Monographs are rule books that establish the permitted indications, strengths and dosing information for any product containing the covered ingredients. Each monograph allows for the marketing of hundreds of thousands of products, unlike the NDA process which authorizes the use of only one product. Products meeting the specifications of a monograph can be marketed without the FDA review. The Monograph system covers 800 active ingredients for over 1,400 different uses and more than 100,000 products. Each monograph is established by regulation. Currently, other than the Sunscreen Monograph, there are over 150 OTC regulations on the books. The Monograph system is the largest and most complex regulatory program ever undertaken by the FDA.

Dr. Mahoney reviewed the need for user-fees to support FDA and has indicated that Dr. Tom Price, the FDA commissioner, has already petitioned Congress to approve his request for user-fees.

In Other News...

Among the non-regulatory developments, DNA material made by US scientists apparently becomes more UV absorbing the longer it is exposed to light. A team of

scientists from Binghamton University had already established that self-assembled DNA films could absorb UV light.¹ They recently discovered that as the films were exposed to more UV, the better they got at attenuating the light.² Apparently, as the films are exposed to UV light, new bonds between the DNA chains develop, chang-



There may be reason for the industry to smile after a productive meeting with the FDA.

ing the material’s crystal structure, resulting in hyperchromicity by increasing its ability to absorb and scatter light. The research focused on this material’s ability as a wound covering. The transparent DNA films (natural material in our bodies that is likely not to be toxic) are currently undergoing biological testing due to their ability to keep the skin hydrated as the material is promoting faster healing.³ The researchers also hope that this material will one day work as an everyday sunscreen which could curb worries over the safety of our current UV protectants. Unfortunately, this material cannot currently be applied in an emulsion, which would require the compounds to be soluble or finely dispersed in order to form a continuous film that is crucial for UV protection. The research and testing for commercialization of this concept as protectors of sunlight overexposure is still a way’s off but is in the right direction.

Researchers at the University of Wisconsin found that applying certain types of sunscreens (octisalate and homosalate) to mice with a multiple sclerosis-like (MS) condition dissipated the symptoms of the condition. Even though the researchers

did not know why those two UV filters had an impact on MS conditions in mice, they speculated that perhaps it was due to the lower levels of cyclooxygenase found when the salicylates were applied. The cyclooxygenase enzyme is very often found in the lesions that MS produces. Researchers hope to determine if it is the UV filters themselves or the sun protection that is the contributing factor here.⁴

Oxybenzone (benzophenone-3) is still in the news as Hawaii considers banning it in order to protect the coral reefs. Even though the bill did not pass in the legislature this year, supporters are determined to try again in 2018.⁵ Research conducted by Dr. Craig Downs of the Haereticus Environmental Laboratory (HEL) has compelled environmentalists, marine biologists, scuba divers, surfers and ocean conservationists to

urge governing bodies and the personal care product industry to make progressive movements for Earth’s protection. Finally, several Californians apparently sprayed sunscreens directly into their eyes to protect themselves from the hazards of the total eclipse of the sun last month, rather than buying the recommended proper eyewear. It seems that we still have some education to do out there on the proper application of sunscreens. Hopefully, those Californians will read the directions before the next eclipse.⁶ ●

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