Cannabis in Cosmetics

Is the hallucinogen of the 1960s, the new biotech answer in beauty?

By Sharon Blinkoff, Locke Lord USA, & **Craig Weiss,** CPT Labs

Cannabis has had a checkered regulatory history in the U.S. First it was taxed, and then essentially banned by its Schedule 1 listing under the Federal Controlled Substances Act, a designation of Category 1 listing effectively criminalized any activity involving cannabis. This includes activities of selling, using, growing or conducting research or any related banking activity. Research activities, unless specifically approved by the U.S. Drug Enforcement Authority and the FDA, would also be criminal.

The category 1 listing of these ingredients was based on the high risk of abuse from the hallucinogenic properties of delta-9 tetrahydrocannabinol (THC), a component which is present in high concentrations in marijuana and low concentrations in industrial hemp. However, because of the definition, the hemp version of the plant should have been excluded from category 1 on the Drug Enforcement Agency (DEA) listing of these products. In 2003, the DEA, the agency responsible for enforcing the Controlled Substances Act, announced it would permit use of industrial hemp in cosmetics and personal care products. The DEA, in granting the exemption, remarked that the low concentrations of THC in industrial hemp present a low risk of "getting the skin high" in cosmetic products.

In the same public announcement, DEA said it was permitting the use of industrial hemp in other products such as fabric for clothing. What is interesting to note is that while the DEA recognized that industrial hemp presented limited to no risk as a hallucinogen, no action was taken to reclassify industrial hemp in the U.S.

In 2014, Congress passed the first Farm Bill that legalized the growing of industrial hemp in the U.S.; however, the regulatory scheme proposed by the 2014 bill was so complex, that cultivation of industrial hemp did not begin in any meaningful way. In 2018, a second Farm Bill was passed which legalized growing industrial hemp in the U.S. and legalized the use of substances derived from industrial hemp including CBD. While industrial hemp and CBD from industrial hemp were legalized by the 2018 Farm Bill, the legislation did not amend the U.S. Food, Drug and Cosmetic Act (FDCA), which meant that while hemp and CBD from hemp were legalized, use of these materials in products regulated by the U.S. Food and Drug Administration (FDA) would remain with the FDA and be subject to compliance with the agency's regulatory requirements for the applicable class of product, as determined by the product's intended use, as evidenced by the product's claims.

While there is limited evidenced-based science on the safety and efficacy of these cannabis materials, there is a strong public perception of great and varied utility with limited risk, because these are natural substances. The demand for legalization of CBD is high and there is

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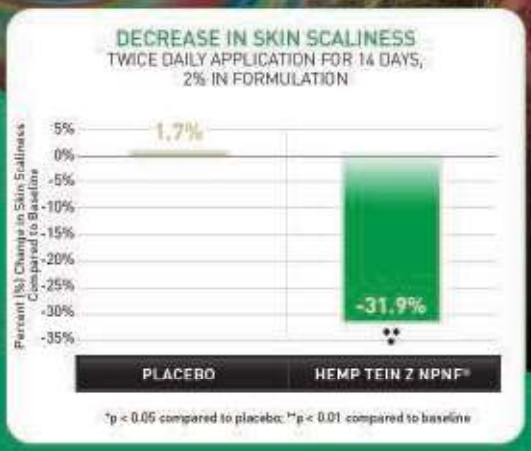

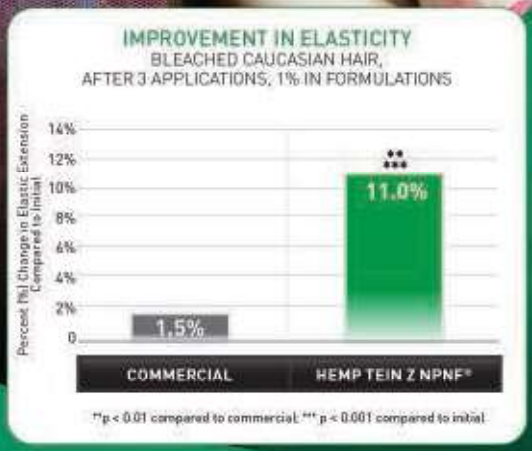

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considerable interest in the 80 or more other biologically active substances in cannabis. These materials are being researched and there are incredible estimates of what the cannabis market will mean with all of these substances and uses. Estimates in the near term are in the billions of dollars a year range and climbing, as are products that propose to use these materials which are coming onto the market at a fast pace.

There is increasing focus on CBD, too, as it was legalized by the 2018 Farm Bill. The potential value of the market which is estimated in the hundreds of billions of dollars is also a driver. The pressure to review and approve uses for these materials will continue to grow and, perhaps, make these materials the new frontier of medical science and biotech.

STATE ISSUES

As a result of the public pressure for access to these cannabis substances and the delay in the Federal Regulatory system to permit access to CBD products, and cannabis use in general, a number of states have passed their own laws permitting medical and recreational use of marijuana and the substances found in marijuana and industrial hemp plants. It should be noted that state legalization of a product applies only within the individual states which have passed these laws. For purposes of national distribution, marketers must comply with both the Federal law as well as any additional requirements imposed by state laws where the product is distributed and sold.

For example, Utah has a requirement that all products containing cannabis ingredients, including industrial hemp, be registered with the Utah Department of Agriculture. A marketer distributing product in Utah must comply with the Utah registration requirements. Another example of required state compliance is California's Proposition 65 law which requires products containing ingredients that appear on its Prop 65 list also label their products with required warning statements. Failure to comply can result in significant fines.

As with all cosmetic ingredients, formulators should be comfortable with their CBD suppliers.

PERMITTED USES

Since marijuana is still listed on the Controlled Substances list, neither marijuana nor any substances derived from marijuana may be used in products distributed nationally, unless the use is specifically approved by the FDA and the DEA. However, in those states that have legalized marijuana, marijuana can be used as permitted by state law. And, as provided in the 2018 Farm Bill, industrial hemp may lawfully be grown and used nationally in the U.S., including use in FDA-regulated products, provided the hemp material meets the U.S. definition of industrial hemp and does not contain levels of THC which are over .3%.

Use of industrial hemp as a drug or use of any substances derived from industrial hemp as a drug would follow the FDA regulatory pathway required for obtaining approval of a New Drug Application, consistent with the procedures and studies conducted for Epidiolex of robust preclinical testing and clinical studies. Epidiolex was approved by FDA in 2018 for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Any OTC use would again follow the NDA application process with the additional requirement of demonstrating that the proposed drug and its indication are suitable for self-medication and self-identification of the condition for which the drug is to be used.

While industrial hemp and CBD from industrial hemp have been legalized, the FDA has taken the position by law that these materials cannot be used in dietary supplements because an NDA was filed prior to the proposed dietary supplement use, which would render the product and use outside the definition of a dietary supplement.

As for food use, the FDA has approved hempseed-derived substances in three food additive petitions which well identified the substances present in the product, and documented that only trace amounts of or no THC or CBD were present. While some states have, as noted, passed their own laws on use of these cannabis substances in a wide array of products including medicinal, food, beverage and supplement use, the FDA has, in the food and supplement area, convinced at least one state not to permit uses of these cannabis materials in food until the FDA approves the uses.

Cosmetic use of industrial hemp was approved in 2003. The Farm Bill extended the permitted uses by permitting CBD found in industrial hemp. As with any cosmetic product, the marketer is responsible for establishing both ingredient