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Safety and Regulatory Authority to Use Flavors: Focus on Vaping Products

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A variety of vaping products are available on the market including "electronic nicotine delivery systems" (ENDS), "electronic cigarettes" ("e-cigarettes"), and other devices that provide the means by which the user inhales vapor from a mixture of constituents that may include nicotine, flavorings, cannabis derivatives, and other materials.

The Flavor and Extract Manufacturers Association of the United States (FEMA) has for more than 50 years sponsored an extensive program, the FEMA GRAS program, to assure the safety of flavor ingredients added to food through state-of-the-art safety evaluations conducted by the FEMA Expert Panel. The Expert Panel operates under the authority of the GRAS ("generally recognized as safe") provision in the statute that governs the safety and labeling of foods, the Federal Food, Drug, and Cosmetic Act ("FFDCA"). The primary route to regulatory authority to use flavor ingredients in the U.S. for addition to food is the GRAS determinations made by the FEMA Expert Panel.

The FEMA Expert Panel evaluates the safety of flavor ingredients only under their conditions of intended use in food and does not evaluate flavor ingredients for use in vaping products, or any other uses that are intended for inhalation. Therefore, FEMA GRAS status for the use of flavor ingredients in food does not provide regulatory authority to use flavor ingredients in vaping products.

FEMA does not support the use of flavors in vaping products in the absence of rigorous safety assessments performed by vaping product manufacturers and marketers that demonstrate safety for this use. The manufacturers and marketers of vaping products, and all other flavored tobacco products, and flavor manufacturers and marketers, should not represent or suggest that the flavor ingredients used in these products are safe because they have FEMA GRAS status for use in food because such statements are false and misleading.

Regulation of nicotine-containing vaping products by FDA

In 2016, the Food and Drug Administration (FDA) published regulations to deem nicotine-containing vaping products, and certain other products, as tobacco products, and designated flavors as "components" of these products. (81 Fed. Reg. 28974. 10 May 2016). The regulations also require that manufacturers of all e-cigarettes and ENDS products must receive authorization from FDA to market the product consistent with the standard that the product is appropriate for the protection of public health when compared to the risks associated with the product's use.

In March 2018, FDA published a notice seeking information on the role flavors play in tobacco products (83 Fed. Reg. 12294. 21 March 2018), and in August 2019 the agency requested information on nineteen potentially harmful constituents in vaping products (84 Fed. Reg. 38032, 5 August 2019). FEMA provided comments on both notices (here and here) reiterating its long-standing position that FEMA GRAS status for flavor ingredients does not apply to flavors used in vaping products.

Recent FDA Action

In January 2020, the FDA released final guidance on its enforcement policy regarding flavored e-cigarettes and other electronic nicotine delivery systems (ENDS). FDA's guidance states that within 30 days of publication of the guidance release date (6 February 2020), flavored cartridge-based e-cigarette and ENDS products, except for tobacco- or menthol flavored products, will be subject to prioritized enforcement. Importantly, FDA is limiting the prioritized enforcement to cartridge-based products, which are those enclosed units sold as cartridges or pods and designed to fit within or operate as a part of an electronic nicotine delivery system and not to open tank-based ENDS products which are typically larger systems sold at retail vape shops and may be customized by consumers.

FDA's guidance also reminds manufacturers that wish to market ENDS products, including flavored e-cigarettes or e-liquids, that they are required to submit a premarket application for specific flavored ENDS products by 12 May 2020 demonstrating that the products meet the standard for marketing authorization – whether the product is appropriate for the protection of public health when compared to the risks associated with the product's use. The agency intends to prioritize enforcement actions against manufacturers of any ENDS product that is offered for sale after 12 May 2020 for which the agency has not received a premarket application.

FDA's updated enforcement policy also addresses the agency's intention to continue prioritizing enforcement against ENDS product manufacturers that fail to take adequate measures to prevent access to minors (ex., age-verification procedures) or those manufacturers whose ENDS products are targeted to minors or whose marketing is likely to promote use by minors.

Vaping-Associated Lung Injuries

The U.S. Centers for Disease Control and Prevention (CDC) has reported that more than 2,600 people in the United States have developed significant lung injuries from the use of vaping products, and more than 30 people have died (Krishnasamy et al., 2020). These lung injuries are referred to as "electronic-cigarette, or vaping product-use associated lung injury" (EVALI). A significant majority of people suffering from EVALI consumed vaping liquids that contained tetrahydrocannabinol (THC), the psychoactive compound in marijuana. While CDC has not definitively established the causative agent or agents for EVALI, it noted that analyses of many THC-containing vaping products have identified potentially harmful constituents such as vitamin E acetate, medium chain triglyceride oil, and other lipids. CDC identified vitamin E acetate in the lungs of 29/29 patients diagnosed with EVALI and has stated, "Until the relationship of vitamin E acetate and lung health is better characterized, it is important that vitamin E acetate not be added to e-cigarette or vaping products" (Blount et al., 2019; Krishnasamy et al., 2020).

A much smaller number of people suffering from EVALI reported the use only of flavored nicotine-containing vaping products and the cause of the lung injuries observed in these patients is unclear (Ghinai et al., 2020; Ellington et al., 2020).

References and Recent Publications of Interest

Blount et al. Evaluation of bronchoalveolar lavage fluid from patients in an outbreak of e-cigarette, or vaping, product-use-associated lung injury. MMWR. Vol. 68. 8 November 2019.

Ellington et al. Update: Product, substance-use, and demographic characteristics of hospitalized patients in a nationwide outbreak of e-cigarette, or vaping, product-use-associated lung injury – United States. MMWR. Vol. 69. 14 January 2020.

Ghinai et al. Characteristics of persons who report using only nicotine-containing products among interviewed patients with e-cigarette, or vaping, product-use-associated lung injury – Illinois, August-December 2019. MMWR. Vol. 69. 24 January 2020.

Hua et al. Identification of cytotoxic flavor chemicals in top-selling electronic cigarette refill fluids. Nature.com/scientific reports. 9:2782. 2019.

Hua et al. Health effects associated with electronic cigarette use: Automated mining of online forums. Journal of Medical Internet Research. 22, 1. 2020.

Krishnasamy et al. Update: Characteristics of a nationwide outbreak of e-cigarette, or vaping, product-use-associated lung injury – United States. MMWR. Vol. 69. 17 January 2020.

Note: Numerous publications on this subject are cited in previous versions of this report and are available upon request.

For More Information

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