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## E-CIGARETTES: FREQUENTLY ASKED QUESTIONS

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### THE BASICS

#### What is an e-cigarette?

**A**n e-cigarette is an FDA-regulated electronic nicotine delivery system (ENDS). E-cigarettes consist of two major components: e-liquid that is vaporized and inhaled, and hardware including the battery, the coil (used for vaporizing the e-liquid) and the container (or chamber). E-cigarettes can be divided into two main categories: closed and open systems. There are important distinctions and advantages to each type.<sup>1</sup>

Closed-system e-cigarettes reach the consumer as a finished product that cannot be modified once it leaves the manufacturer—the battery, coil and chamber holding the e-liquid are self-contained. These are the types of e-cigarettes generally sold in convenience stores. One advantage of closed systems is that they don't require much working knowledge on the part of the user. And because they are generally sold alongside combustible cigarettes, closed-system e-cigarettes are more visible to smokers who may be willing to switch to a safer product.

In contrast, many aspects of open-system devices can be customized to suit the user, including flavor and nicotine strength. Open-system devices and the e-liquids they use are mainly sold in specialty vape stores. One advantage of open-system devices is that customizable nicotine strength and flavors enable users to distance themselves from the experience of combustible cigarettes. The other advantage is that, as of January 2020, e-liquids used for open systems are still available in flavors other than tobacco and menthol, while e-liquids used for closed systems are not.<sup>2</sup>

#### Are they safer?

Public Health England, the United Kingdom's leading public health agency, has stated that e-cigarettes are unlikely to exceed 5 percent of the risk associated with combustible cigarettes.<sup>3</sup> These products are recognized as presenting a reduced risk because they don't employ the traditional cigarette combustion process that releases around 7,000 chemicals.

#### Do they help people quit?

The use of e-cigarettes as a quit tool remains controversial. However, studies consistently indicate that among those who use e-cigarettes to quit smoking, nearly twice as many are successful compared to those who choose nicotine replacement therapies (NRT). In the United Kingdom, e-cigarettes are more popular than traditional quit methods (varenicline, NRT or counseling).<sup>4</sup> In fact, Public Health England specifically endorses e-cigarettes as a cessation tool.<sup>5</sup> While not officially approved as a cessation product by the FDA, they are also gaining popularity in the United States, with a higher degree of success for long-term cessation.<sup>6</sup>

#### What about vaping-related illnesses?

The term "e-cigarettes" refers to products that contain nicotine, and e-cigarettes containing nicotine have not been identified in any vaping-related illness reported between March 2019 and January 2020.<sup>7</sup> Vaping illnesses have been strongly linked to Vitamin E Acetate, which is present in some THC-containing vaping products, often called dabs or vape pens.<sup>8</sup> As of January 2020, both the FDA and the Centers for Disease Control have removed their warnings regarding e-cigarette use in relation to vaping illnesses.<sup>9</sup>

## REGULATION

### Are e-cigarettes currently regulated?<sup>10</sup>

The FDA has jurisdiction over all tobacco products—including e-cigarettes—under Section 901(b) of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).<sup>11</sup> While e-cigarettes do not actually have tobacco in them, they are considered a tobacco product. According to the FDA, products that are made or *derived* from tobacco and intended for human consumption are considered tobacco products.

This means that for a product to be legally sold under federal law, the FDA must have expressed approval of that product. Conversely, any sold or distributed tobacco product that has not been granted approval by the FDA is, by definition, illicit.

### What are e-cigarette manufacturers required to do?

Right now, for e-cigarette products to be sold legally, they must have been introduced to the market before Aug. 8, 2016.

E-cigarette manufacturers must be registered with the FDA, and manufacturers must provide the FDA with a products list, including lists of ingredients, components and additives. They must also provide the FDA with e-cigarette labeling and advertisements.

Furthermore, as data is collected, manufacturers must provide the FDA with tobacco health documents that include the health, toxicological, behavioral and/or physiological effects of current or future tobacco products and their constituents (including that of the vapor).

Finally, all e-cigarettes must include a warning statement on packages and advertisements for ENDS stating, “WARNING: This product contains nicotine. Nicotine is an addictive chemical.”

## FUTURE REQUIREMENTS

### What else is the FDA doing?

All e-cigarette manufacturers must submit their premarket tobacco applications by May 12, 2020 or they will be removed from the market. Manufacturers that submit e-cigarette applications by May 12, 2020 will be allowed to continue sales and marketing while the FDA processes and reviews applications.<sup>12</sup> The FDA has 12 months to review and process applications; those that are approved will be allowed to continue sales and marketing, while those that are not will be removed from the market.

During this time, and at all times, the FDA has the authority to remove products from the market that are in violation of FDA regulations.<sup>13</sup>

## PMTA PROCESS<sup>14</sup>

### What is a PMTA?

The Premarket Tobacco Application (PMTA) process allows manufacturers or distributors of new tobacco products—including e-cigarettes—to seek marketing approval of their products. On its face, the PMTA process is actually quite simple. Manufacturers are allowed to submit applications to sell new tobacco products and, if approved, they will be able to market the product.

## How are PMTAs reviewed?

The primary consideration in reviewing applications is a public health test. This means that manufacturers must demonstrate that marketing of the products would be appropriate for the protection of the public health. That standard requires the FDA to consider the risks and benefits to the population as a whole, including whether availability of the product will increase the likelihood that non-users will start using such products.<sup>15</sup> The agency's evaluation also includes reviewing a tobacco product's components, ingredients, additives, constituents, toxicological profile and health impact, as well as how the product is manufactured, packaged and labeled.

The FDA considers each ENDS product with a different flavor variant or nicotine strength to be a different product.<sup>16</sup> So, for example, the FDA might approve some flavors or nicotine strengths in a brand's product and reject other flavors or nicotine strengths from the same brand.

## FLAVORS

### Are e-cigarettes allowed to be flavored?

The FDA has recognized the potential for flavors in some tobacco products to confer a public health benefit: "We recognize that the availability of alternatives to traditional tobacco flavors in some products (*e.g.*, ENDS) may potentially help some adult users who are attempting to transition away from combusted products."<sup>17</sup>

Characterizing flavors are banned in cigarettes under Section 907(a) of the Tobacco Control Act,<sup>18</sup> and there is increased interest in applying this standard to other tobacco products that were previously exempt—including cigars and now e-cigarettes. In January 2020, the White House issued an order to ban flavors other than tobacco and mint in closed systems, while flavors in open systems remain legal. This ban was imposed in response to increased concerns that youth use of e-cigarettes is driven by the availability of flavors in closed systems, which are considered to be more easily available than open-system e-cigarettes. It is important to note that characterizing flavors are not ultimately banned in e-cigarettes, leaving the possibility that flavored e-cigarettes could be back on the market if the FDA approves PMTAs of flavored e-cigarettes. This could only happen if the FDA considers a specific flavor of a specific e-cigarette to meet the public health standard.

### What are states doing?

As states and municipalities seek to address youth use of e-cigarettes, many have proposed either full e-cigarette bans or bans on flavored e-cigarettes. As the FDA reviews applications for e-cigarettes, it is likely that many will be granted marketing approval—and those that are granted approval will have met the public health test demonstrating that availability of the product is for the benefit of public health. This may well impact states that choose to ban the entire product category or an aspect of the category, such as non-tobacco flavors, before full review by the FDA.

## CONTACT



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