Evaluation of Novel, Oral Tobacco-Derived Nicotine Products for HPHCs


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Abstract

VERVE® Discs and Chews are oral, non-dissolvable, tobacco-derived nicotine products. In May 2016, the U.S. Food and Drug Administration (FDA) issued a final rule to deem e-cigarettes, cigars and all other tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Manufacturers of regulated tobacco products are required to report to FDA quantities of Harmful and Potentially Harmful Constituents (HPHCs) by November 8, 2019. FDA has not issued specific guidance for reporting HPHCs for novel tobacco products, such as VERVE®, as they have for certain other regulated tobacco products. Absent specific guidance from FDA, we measured VERVE® according to the requirements for smokeless tobacco, recognizing that these products do not meet the statutory definition of a smokeless tobacco product. The objective of this work was to measure HPHCs in VERVE® Discs and Chews products over time and compare to the levels of analytically available oral tobacco products and an oral nicotine replacement therapy (NRT) product. Results: No detectable levels or significant reductions in HPHCs compared to other oral tobacco products and comparable HPHC results to the NRT.

Background

• To date, FDA has not issued specific guidance regarding reporting of HPHC levels in novel products such as VERVE®. Even though these types of products do not meet the definition of a "smokeless tobacco product" (i.e., they do not consist of cut, ground, powdered, or leaf tobacco), we applied the abbreviated list of HPHCs for smokeless tobacco from the 2012 Draft Guidance, Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act.

• This study establishes the levels of HPHCs in VERVE® Discs and VERVE® Chews and also provides a comparison to other tobacco products as required under section 910(b)(1)(C) of the FD&C Act.

Methods

Chemical analyses of VERVE® products demonstrated low levels of HPHCs. Differences in HPHC levels (e.g., arsenic or cadmium) between product format (disc or chew) are possibly related to differences in manufacturing and packaging conditions rather than differences in the tobacco product itself. Differences in HPHC levels (e.g., arsenic or cadmium) between VERVE® Discs and VERVE® Chews products than levels found in cigarette smoke with the exception of cyanogen. Additionally, the levels of HPHCs in the products are lower than those reported for the recently FDA authorized General® snus products.

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References


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