



Lead by Sales, LLC d/b/a White Cloud Cigarettes

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**Comment Submitted in Response to FDA Regarding Proposed Rule**

**Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for**

**Tobacco Products**

**Docket ID: FDA-2014-N-0189**

**Written Statement, presented by: Robert Burton, Director, Corporate & Regulatory Affairs, White Cloud Electronic Cigarettes**

Thank you for allowing us the opportunity to submit comments to the aforementioned Deeming Regulations, on behalf of Lead By Sales LLC (dba White Cloud Electronic Cigarettes) and the range of products currently marketed by our company under the White Cloud brand. I would like to utilize this written submission as an attempt to address some of the questions raised by the FDA.

Firstly, as some background, White Cloud is a Florida-based, vertically integrated, manufacturer, marketer and distributor of our own developed and branded electronic cigarettes. We were founded in 2008, employ approximately 80 people and had a gross turnover for 2013 of \$15million through mainly internet-based sales.

We have a long-term research agreement with the University of South Florida and have recently been awarded the Tampa Bay Times' "#1 Small Business" in the Tampa Bay Area for 2014.

At White Cloud, we agree with many professionals and experts in the area of public health who see the potential for electronic cigarettes to significantly reduce the harm and risk associated with existing combustible tobacco use. The recent Deeming Regulation issued by the FDA has a number of key elements, such as underage restrictions, no ban on internet sales or flavors and the requirement to submit ingredients and new products for review, which we fully support.

As the industry currently stands, there is wide variation in electronic cigarettes, their quality and individual company approaches to marketing to consumers. As such, we at White Cloud support the intent behind the FDA Deeming Regulations that propose the

submission of ingredients and the review of any product entering the market. However, we do not feel that this should be unduly restrictive or prohibitive for companies, such as ourselves, that, whilst doing all within their power to produce products to the highest available standard, do not have the resources and experience available to us that may be readily available in larger competitors (such as “Big Tobacco”).

Having said that, we fully agree that future regulation of electronic cigarettes should be science and evidence-based with appropriate product and manufacturing standards, thus ensuring the maximum quality of product whilst providing current tobacco consumers with a significantly lower risk alternative to existing combustible tobacco products.

The specific regulatory areas to be addressed with respect to electronic cigarettes should not restrict the opportunity for consumers to make an educated decision relating to their future health risks, but should give Public Health and Regulators alike confidence that the products meet acceptable quality, safety and efficacy standards. We believe that the ingredient submission and new product review process detailed in the FDA’s Deeming Regulations are a positive step in the direction of safety, quality and consistency, as long as such regulations are respectful of the efforts made and resources available to companies operating at all levels of the economic spectrum.

We also support the FDA in their aim to limit access of electronic cigarettes to those over the age of 18. In fact, at White Cloud, we have had such restrictions in place since we started business five years ago and have developed (and implemented) bespoke and sophisticated software in order to make sure that only adult consumers are able to purchase electronic cigarettes via our online order system.

We believe that any regulation of electronic cigarettes should be based on peer reviewed and published scientific evidence and be developed in consultation with both electronic cigarette manufacturers and other relevant stakeholders, such as public health experts. We were encouraged to hear that the FDA will base their decisions on the implementation of this Deeming Regulation, and future regulatory developments, on scientific evidence and not restrict specific elements, such as flavors, without supportive data.

Our range of flavors has been developed based upon direct feedback and suggestions from our consumers. This range of flavors and ingredients are also manufactured in the US to the highest product standards. Contrary to much of the unsupported claims that our products are made “attractive to youth”, we in fact use adult focus groups and research partners (such as the University of South Florida) to ensure that our products and practices focus upon adult smokers.

As previously mentioned, we have a state-of-the-art age verification system that has been presented to the FDA’s Center for Tobacco Products at several “Listening Sessions” throughout its development. This system, combined with our fully integrated structure (we do not sell through 3<sup>rd</sup> party retailers) ensures that we minimize the potential for underage purchasing. In fact, I would like to draw to your attention the fact that, in March alone, the FDA issued over 330 warning letters to Tobacco retailers in connection with

sales to minors of tobacco products; an area that has been under their control now for 5 years: There are clearly benefits to being vertically integrated such as White Cloud.

In terms of child safety regarding access to nicotine, we at White Cloud do not produce re-fillable devices that have the potential to lend themselves to abuse, but instead manufacture our cartridges and electronic cigarettes to the highest possible level (and to our own design). Our products are constantly being tested to ensure they do not leak and prevent the potential for abuse. In fact, in the last two weeks, we have started our US-based automated manufacturing; something that will bring our products under even tighter direct control.

We fully support the FDA's desire to bring product standards to this product category and, in anticipation of this, our production facility is already ISO accredited.

We totally agree that safety of our children is of paramount importance, which is why our products are made to such exacting standards.

Of course, I cannot answer for the rest of the industry, but we, at White Cloud, take our responsibility extremely seriously and have developed and launched our own science website aimed at communicating the facts about nicotine, our products and any published "peer-reviewed" science relating to this area.

Furthermore, we have made other commitments to raising the standards and science in this category, such as joining CORESTA, to ensure the development of standardized test methods.

As previously mentioned, our commitment to developing an ethical and robust business has resulted in a long-term research agreement with the University of South Florida and being voted "#1 Small Business" in the Tampa Bay Area, by the Tampa Bay Times" for 2014.

I know that it is not always easy to convey commitment and sincerity via a letter, but I certainly want to assure you of ours.

Yours sincerely,



Robert Burton

Director, Corporate & Regulatory Affairs