



October 14, 2015

Dr. Janet Woodcock  
Director, Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Woodcock:

We write to bring to your attention substantial evidence that manufacturers and sellers of electronic cigarettes and related products may be marketing their products for therapeutic purposes in the absence of review and approval by the Food and Drug Administration, and thus may be selling unapproved new drugs or devices that violate numerous provisions of the Food, Drug and Cosmetic Act (FD&C Act or the Act), including Section 505 and Section 301, as well as the misbranding provisions under Section 502 of the Act.

The evidence was uncovered in a review, by Truth in Advertising (TINA), of more than 150 websites selling electronic cigarettes. See "Smoking Out E-Cigarette Ad Claims," <https://www.truthinadvertising.org/smoking-out-e-cigarette-ad-claims/>. The TINA survey found numerous websites featuring express claims that e-cigarettes help smokers stop smoking. For example:

- **Emerald Lux Electronic Cigarettes:** "Emerald Lux smokeless e-cigarettes are the cleanest, highest quality premium electronic cigarette brand, *crafted to give you the best chance of smoking cessation as you stop smoking traditional cigarettes* and move on to best part of your life." (emphasis supplied).
- **EPUFFER:** "Among traditional nicotine delivery systems available on the market today, the new EPUFFER PVD (Portable Vaporizing Device) also known as electronic cigarette, is a great alternative for those who wants to cut-down on tobacco product intake. EPUFFER has been featured on many television and radio networks including The Doctor's TV show where it was rated as one of the top health trends of 2009. In March of 2010, it was re-evaluated and *recommended as a quit smoking device that may help smokers more easily abstain from smoking.*" (emphasis supplied).
- **SmokeZero:** "Smoke-Zero vs. Smoking Alternatives: Why do most smoking alternatives fail? Habit. While the pill, patch, gum, and even hypnosis help deal with the nicotine

cravings they do nothing to help you with the habit of smoking. Sayings like ‘I just smoke while I drink,’ or ‘I like a smoke after a meal’ are the exact reason why these methods most often fail. Bottom line, you can’t smoke a pill, patch or gum, so how could they help you with the habit?! *Smoke Zero works on the Addiction and the Habit. What’s different about Smoke-Zero? Smoke-Zero Electronic Cigarettes work on both the nicotine addiction and help the habit. All the time we get emails from one and two pack per day smokers who are successfully using exclusively Smoke-Zero Electronic Cigarettes.*” (emphasis supplied).

- **EVCigarettes:** “Many people looking into how to quit smoking have given up on various methods such as the patch, nicotine gum, or even going cold turkey, but have found that *vaping with electronic cigarettes actually makes the transition off of traditional cigarettes easier.*” (emphasis supplied).
- **Veppo:** “This new age invention simulate the taste, feeling and presence of smoking—so much, that many smokers have successfully stopped smoking and taken up vaporizers as a better lifestyle alternative...It will feel like you’re really smoking and *will address the chemical dependency.*” (emphasis supplied).
- **Henley:** “It was cool to see the use of our ecigs reducing the amount of traditional cigarettes people were smoking and helping them quit completely.” (quote from co-founder).

Other e-cigarette websites make prominent use of testimonials to make therapeutic claims. For example:

- **Smart Smoke:** “My husband and I have been on the Smart Smoke system for three months, and we love it! We were both smokers for nearly 20 years, and now neither of us can stand the smell of cigarette smoke. We are both extremely grateful to Smart Smoke for giving us our lives (and our health!) back. *We would both highly recommend Smart Smoke to anyone who is trying to quit smoking.*” (emphasis supplied).
- **777 ECigs:** “My husband and I have both been consistent smokers for over 12 years. Neither of us really enjoyed being smokers but it had been such a part of our lives for so long we felt we would never stop. *Thanks to 777 ecigs we are tobacco free!*” (emphasis supplied).
- **Magic Mist:** “E-cigarettes changed my husband from a 2-pack a day smoker and stroke victim to a non-smoker.”
- **ELUMA Cigs:** “I’m a smoker for more than half my life and tried so many times to quit using several different methods but smoking had me in its grips no matter what I did. *I finally found my cure for a terrible habit. Haven’t touched a cigarette in over 2 weeks.*” (emphasis supplied).

These examples are typical of the numerous therapeutic claims being made by marketers of electronic cigarettes. Such claims render these and similarly marketed products “drugs” under Section 201(g) of the Act that cannot be marketed without approval of a new drug application as required by Section 505 of the FD&C Act. These products may also fit the definition of “devices” under Section 201(h)(2), and therefore cannot be sold without premarket approval under Section 515 of the Act.

The TINA Survey suggests that violations of federal law on a massive scale are taking place in the marketing of e-cigarettes. We therefore urge FDA to immediately commence an investigation of the claims being made by these companies and take prompt and appropriate enforcement action against those found to be violating the law.

Investigation of these website claims, and appropriate enforcement action, should not await completion of the rulemaking recently commenced by FDA to further describe the circumstances in which a product made or derived from tobacco will be subject to FDA regulation as a drug, device or combination product.<sup>1</sup> As FDA observes in its discussion of the proposed rule, “...claims related to smoking cessation have long been recognized as claims conferring drug or device jurisdiction.”<sup>2</sup> FDA’s proposed rule does not contemplate a change in the treatment of smoking cessation as a therapeutic claim. Thus, under the proposed rule, and under any defensible interpretation of FDA’s drug/device jurisdiction, the claims made on these e-cigarette websites subject these products to that jurisdiction and render these companies in violation of the FD&C Act. Enforcement of the statute against these products need not await any further clarification of that jurisdiction by FDA.

Sincerely,

American Cancer Society – Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

Cc: Mitchell Zeller, Director, FDA Center for Tobacco Products

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<sup>1</sup> 80 Fed. Reg. 57756 (Sept. 25, 2015).

<sup>2</sup> *Id.* at 57759.