DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

February 27, 2012

[redacted]

Our Submission Tracking Number (STN): SD0000015

[redacted]

The Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) understands that you are a manufacturer of electronic cigarettes ("e-cigarettes") including e-liquid. We are writing you and other manufacturers to request information relating to the safety of electronic cigarettes.

As background, the Family Smoking Prevention and Tobacco Control Act[1] (Tobacco Control Act), which amends the Federal Food, Drug, and Cosmetic Act (FD&C Act), was enacted on June 22, 2009, and it provides the FDA with authority to regulate "tobacco products." Although the statute places certain "tobacco products" (i.e., cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) immediately under the general controls and premarket review requirements in Chapter IX, it also permits FDA, by regulation, to extend those controls to other categories of "tobacco products." The Agency has announced[2] that it intends to propose a regulation that would extend the Agency's "tobacco product" authorities in Chapter IX of the FD&C Act, to e-cigarettes and other categories of tobacco products that meet the statutory definition of "tobacco product" in Section 201(rr) of the FD&C Act.

As noted above, we are interested in learning more about the safety of e-cigarettes. Therefore, we are requesting that you submit the following information to us relating to e-cigarette and e-liquid products manufactured both past and present:

1. For products you manufactured, submit a summary of the consumer complaints and adverse event reports you have received including the number of occurrences and the outcome of your investigations.
2. For products you manufactured, submit a summary of reports of e-cigarette misuse, the consequences to the user if any, the number of occurrences, and the outcome of your investigations.

[1] An overview of the Tobacco Control Act is available at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm246129.htm
[2] The FDA Letter to Stakeholders is posted at http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm

3. For products you manufactured, describe product labeling and systems you have in place, if any, to facilitate reporting and review of consumer complaints and adverse events.
4. For products manufactured and distributed by other companies, submit information you are aware of regarding consumer complaints, adverse events, and misuse..

We request that you submit your response to CTP by April 30, 2012. Please organize your response according to the numbered items above. The submission should be prominently identified with the label "SD0000015 FDA E-cigarette Request" and sent to the following address:

Center for Tobacco Products
Food and Drug Administration
Attn: Document Control Center
9200 Corporate Boulevard
Rockville, Maryland 20850

Thank you for your consideration of this request. Please contact Idara Udoh, Regulatory Health Project Manager, by email at idara.udoh@fda.hhs.gov and at (301)796-3074 if you have questions.

Sincerely,

David L. Ashley, PhD
Director, Office of Science
Center for Tobacco Products