May 22, 2017

Division of Dockets Management
Food and Drug Administration
5639 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. FDA-2016-N-4232 – Comments to Docket on “Battery Safety Concerns in Electronic Nicotine Delivery Systems (ENDS) Public Workshop”

Altria Client Services LLC (ALCS), on behalf of Nu Mark LLC (Nu Mark)¹, submits these comments regarding the Battery Safety Concerns in Electronic Nicotine Delivery Systems (ENDS) Public Workshop hosted by the Food and Drug Administration (FDA) on April 19-20, 2017. These comments supplement the presentation and panel comments made by ALCS representative Doug Burton at the workshop. Furthermore, these comments highlight certain issues that FDA should consider as it gathers information about ENDS battery safety concerns and investigates possible approaches to address those concerns.

Our comments will address the following points:

I. A Systematic Approach to Evaluate ENDS Electronic Safety² is Critical to Mitigating Risks for the Individual User;

II. FDA Should Establish a Process to Recognize Consensus Electronic Safety Standards for ENDS Battery Systems; and

III. FDA’s Premarket Approval Product Pathways Should Provide Accelerated Review Processes so That Innovations and Enhancements in Battery Safety can be Rapidly Incorporated into ENDS Products.

I. A Systematic Approach to Evaluate ENDS Electronic Safety is Critical to Mitigating Risks for the Individual User

The safety and quality of e-vapor products is of paramount importance. As a result, ALCS, on behalf of Nu Mark, developed a comprehensive hazards analysis process to evaluate e-vapor

¹ Nu Mark is a wholly-owned subsidiary of Altria Group, Inc. (Altria). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. “We” and “our” are used throughout to refer to Nu Mark, except where the context requires otherwise.

² For purposes of these comments, the use of the phrase “Electronic Safety” means the safety of the electrical, heating, battery and charging systems for ENDS.
device electronic safety. We urge FDA to consider this type of process as it reviews ways to address battery safety concerns.

Lithium-ion batteries are widely used as a power source in portable electrical products and have become ubiquitous in our home and business environment. While the rate of failure associated with their use is small, several well-publicized incidents related to lithium-ion batteries in actual use have raised concerns about their overall safety. Over the past 20 years, rechargeable lithium-ion battery technologies have evolved, providing increasingly greater energy density, greater energy per volume, longer life cycles and improved reliability. Commercial lithium-ion batteries now power a range of electrical and electronic devices, including medical devices, mobile phones, digital cameras, laptop computers, industrial equipment and automotive applications. Test standards are in place for many of these applications that mandate a number of individual tests designed to assess specific safety risks associated with the use of their lithium-ion batteries. Lithium-ion batteries power most ENDS products. An ENDS battery system design that does not recognize and accommodate battery cell performance boundaries can force a reasonably-safe cell into a potentially hazardous operating condition. A systematic device hazards analysis can identify instances where device demands on a battery cell do not align with battery cell capabilities, and enable mitigation of inadvertently designed-in hazards.

In the absence of electronic safety standards for ENDS products, we have designed a systematic evaluation for device designs and potential electronic safety hazards. Figure 1 below illustrates our Hazards Analysis Process.
Figure 1. ALCS Hazards Analysis Process.

**Key Elements of our Hazards Analysis Process**

**E-vapor Engineering**

For in-house-designed e-vapor systems, the process begins with understanding product requirements in order to develop design controls that can inform prototype development. As an initial matter, we need to ensure that the battery cell design is appropriate for its intended application. ENDS battery cells experience high discharge currents when compared to other lithium-ion battery applications like cell phones or computers. If the battery cell is not designed to operate in a high discharge current environment, it can undergo initial and repetitive stresses that can create unsafe conditions internal to the battery cell. If the battery cell becomes internally-defective, device safety components cannot mitigate the resulting risks and consequences. As a result, we focus our efforts on gaining a comprehensive understanding of

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3 For e-vapor systems that are not designed in-house, they enter our hazards analysis process at the Technical Data Package step.
how the mechanical and chemical design of a selected cell will perform for a given ENDS design.

Before actual prototype assembly begins, we subject the design, drawings, bills of material and operating algorithms to an “on-paper” hazards analysis. As an example, the “on-paper” process can evaluate current-handling capability of circuit components (e.g. transistors, diodes, integrated circuits, printed circuit board pads and traces) against their anticipated current exposure in both normal and faulted operating conditions. This allows us to identify potential design issues – and mitigate potential battery cell failures – before we incur time and financial costs that further commercialization entails.

**Third Party Failure Analysis and Review**

Our design controls inform prototype development. Once we have a prototype manufactured, we send it to a third party for design review and hazards testing. Our failure analysis consultants operate under three obligations: Do the right tests, do the tests right, and provide results that are actionable by our engineering and product development teams.

In the absence of ENDS device testing standards, we use the Institute of Electrical and Electronic Engineers (IEEE) Standard 1725 – a standard written for single-cell cell phone battery systems. IEEE 1725 has been an effective standard to test ENDS battery systems against because the usage environment for ENDS is very similar to that for cell phones. For example, ENDS products and cell phones both use a single cell battery, are held close to the face during use, are stored in a pocket between uses, and are often charged on a nightstand or in an automobile. Pursuant to IEEE 1725, our third party failure analysis consultant conducts tests of the battery cell, the battery cell in conjunction with its battery circuitry, the charging system, and any charging accessories the product may encounter. Testing also includes simulating failures of internal and external power systems to evaluate fault tolerance and consequences of system failures. Based on the results of this testing, our failure analysis consultant provides us with a comprehensive report of the test results. Our engineering and product development teams systematically review each result and make design changes; proceed without any changes; update instructions and or warnings, as needed; or decide to discontinue development as appropriate to the potential consequences of each report finding. Regardless of the decision, we archive our learnings to inform future device development work.

**Human Factors Analysis**

We also work with a third party to conduct a human factors analysis. The third party is experienced in failure analysis as well as being credentialed in cognitive sciences; this facilitates a comprehensive evaluation of potential modes of consumer interaction with ENDS products. We use human factors analysis to identify and evaluate usage modes that our product developers may not have anticipated. The results of this analysis inform product design as well user

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4 IEEE is an association of industry and certification body engineers that creates voluntary design guidance consensus standards for electronic devices and systems. The Cellular Telecommunications and Internet Association supports (and many retailers require) certification for cell phone battery systems to these standards.
communications, instructions and warnings, and provide a solid connection between potential ENDS hazards and the user communications designed to mitigate them.

**Battery Cell Procurement and Manufacturing**

In addition to the elements of the hazards analysis process described above, a familiarity with battery cell suppliers, including conducting audits and understanding their processes, products and controls is important to procuring a well-manufactured battery cell. Suppliers of battery cells should, at a minimum, be able to demonstrate manufacturing consistency, traceability, a process for audit-based corrective and preventive actions, and continuous improvement.\(^5\)

In order to reduce the occurrence of ENDS battery adverse events, cell defects should be addressed at the manufacturing level. ENDS devices sometimes employ inexpensive battery cells, which are frequently hand-wound. While this is not necessarily a direct cause of battery failure, in-process inspections and controls must account for the additional potential variability affecting cell reliability and robustness. Manufacturers must ensure that appropriate manufacturing controls and quality systems are in place and executed with diligence.

As FDA considers ways to address ENDS battery safety issues, we urge the agency to rely on or utilize a process such as our Hazards Analysis Process to evaluate ENDS device electronic safety and to mitigate risks for the individual user.

**II. FDA Should Establish a Process to Recognize Consensus Safety Standards for ENDS Battery Systems**

We believe that consensus product safety standards should be established to mitigate battery safety risks in e-vapor products. Developing standards through a consensus process increases predictability and provides a consistent approach to evaluating testing methods, performance criteria, and risk management processes.

FDA should develop a process to recognize consensus safety standards pertaining to ENDS electronic safety, including batteries (e.g., FDA could issue industry guidance). Consensus standards that have been developed by testing laboratories with input from experts and stakeholders should be recognized by FDA as part of the ENDS premarket approval review process.

For example, Underwriters’ Laboratories’ (UL) Standard for Electrical Systems of Electronic Cigarettes (UL 8139) could be such a candidate after it goes through the UL Collaborative Standards Development System. UL has convened a Standards Technical Panel (STP) to begin the collaborative review process, which includes gathering expert input from relevant stakeholders, including regulatory agencies, manufacturers, suppliers, health organizations, consumer advocacy organizations and insurance companies.

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5 Charles P. Monahan, with Panasonic, provided a list of lithium-ion cell criteria (points to consider when designing and manufacturing cells – IEEE1625 and 1725) in a presentation at FDA’s Workshop.
Other standards and electrical technical organizations, including IEEE, use a similar collaborative approach and could help create effective and workable standards for ENDS electrical systems. Regardless of the particular group working to create such standards, the process must include relevant stakeholders.

FDA’s recognition of any such consensus standards should be guided by the following considerations:

- **Consensus Standards Should Focus on Performance Requirements**

  Consensus standards for device safety across the ENDS category should focus on performance requirements, not design requirements. While some design requirements can mitigate battery cell failures – particularly those caused by external faults – the applicability and effectiveness of a specific mitigation design requirement varies widely from device to device. On the other hand, requirements to perform in a safe state and the steps taken to ensure safe performance are constant across all ENDS devices.

- **Performance Requirements Should be Tiered to Control for Both Power Capability and Energy Capacity**

  Performance requirements are necessary to ensure that an ENDS device’s power to discharge during normal use does not exceed the battery cell’s rated power capability. Further, these standards should be tiered to account for the relationship between energy capacity and power capability.

  Lithium-ion product manufacturers select battery cells based on key attributes like energy capacity and power capability. Energy capacity denotes the amount of energy stored in a battery cell (expressed as watt-hours) and affects the number of discharges available per recharge, whereas power capability defines the amount of power a battery can deliver (expressed as milliams or amps) without immediate or accumulated over-stress. Capacity and capability can have an inverse relationship. Potential battery cell failure arises when high capacity batteries are used in high power output applications. This risks the possibility of damaging the cell internally. Performance requirements ensuring that the discharge load during normal use does not exceed the battery cell’s rated power capability can mitigate this failure risk.

  Performance requirements should be tiered with respect to capacity and capability to properly address potential safety issues. Chemistries, arrangements, geometries, and other factors can all affect the capacity to capability relationship; meaning the relationship varies within a given category (e.g., 18650 size) of battery cells.

- **Components and Software Can Mitigate Failures Caused by Non-Internal Battery Cell Defects**

  Implementing design controls in an ENDS device through components or software logic can mitigate failures caused by non-internal battery cell defects. These controls must
demonstrate the reduction of failures resulting from incidents such as connecting batteries to non-specified chargers, overcharging, over discharging or exceeding a battery cell’s power capability, or inadvertent discharging.

- **Temperature Controls in ENDS Vary in Purpose and Effectiveness**

  “Temperature Controls” in ENDS battery systems can take several forms with different objectives and executions:

  - Charge and Discharge Control for Ambient Temperature: Controls charge and discharge current based on ambient temperature to keep the battery cell within its normal operating range to avoid accumulated internal cell damage over time.
  
  - Charge Control for Internal Cell Temperature: Interrupting charge current based on internal cell temperature is used to stop overvoltage, overcurrent or time-driven overcharging to avoid potential thermal runaway. Effective control based on internal cell temperature is difficult because it is not currently technically-feasible to monitor temperature near the center of the cell, where it matters most. Charging “watchdog timers” is one alternate way to interrupt time-driven cell overcharging. Overvoltage and overcurrent protections in the charging architecture can prevent current-driven cell failures.

Positive Temperature Coefficient devices (PTCs) are often used in temperature-based charge control applications. PTCs require careful integration as they cannot sense temperature near the center of the cell and thus may react too slowly to be effective (i.e., they may not be able to “keep up” with the thermal activity in the cell and thus be ineffective).

Increasing cell temperature absent an external cause is indicative of an internal cell fault. Temperature control components are unlikely to have a significant impact in preventing battery cell failure for an internally-defective cell. External temperature influences on battery cell performance should be evaluated during cell testing.

- **Performance Requirements Should Drive Development of Battery Management Units**

  Battery Management is an electronic architectural strategy as much as it is an electronic component. Implementing dedicated battery management units (BMUs) to mitigate battery failure during abnormal operation is effective when the BMU is designed around the battery cell’s capabilities and the device’s performance requirements. The reliability of BMUs can vary; in some cases BMU’s are intolerant of in-circuit currents that occur just when the unit is called-on to perform. Reliable BMUs can require physically-large components to manage currents encountered in power supply failure; thus, dedicated BMUs may not be practicable for some ENDS designs, particularly smaller devices. Design requirements should not be built around a dedicated BMU if adequate protection can be demonstrated in alternate architectures.
• **Performance Requirements Can Mitigate Risks Associated with Inadvertent Activation**

The primary risk presented by inadvertent activation, particularly where the device is unattended and remains in the “locked-on” state, is heat-driven property damage or personal injury. Thus the focus on mitigating inadvertent activation should be performance-based, rather than to require specific design features. Examples of design strategies that can prevent overheating during inadvertent discharge of ENDS devices include:

- Implementing dual activation;
- Enforcing an activation time limit; or
- Placing a maximum temperature limit on device operation, both in normal and “locked-on” states.

A simple and effective way to avoid risks associated with inadvertent activation is to remove the atomizer from an ENDS device prior to packing it for travel, and ensuring that the atomizer connector on the ENDS battery system is covered with a non-metallic material to prevent short circuits.

• **Lithium-Ion Power Tool Requirements Are Not Appropriate for Single Cell ENDS Devices**

Using lithium-ion power tool requirements as a basis for developing ENDS standards would not be appropriate for single cell ENDS devices. While operating modes in these devices may be similar, with short bursts of discharge followed by longer periods of rest and recovery, the battery packs used are quite different. Power tools predominantly use multiple cells in a battery pack to increase voltage while keeping operating current manageable for individual cells in the pack. Multi-cell lithium-ion products incorporate cell-balancing among multiple cells to mitigate potential failures due to cell resistance mismatch and resulting potential overcharging of individual cells; multi-cell ENDS devices require similar balancing systems. Most ENDS devices, however, typically use single cells, so the per-cell operating currents are frequently higher than those encountered in power tools.

• **Proposed Requirements Should Address the Difference Between Replacement Cells and Purpose-Built Battery Packs**

ENDS battery requirements should recognize and address the differences between replacement cells (e.g., general application cells like the common 18650 form factor) and purpose-built battery packs. E-vapor products developed in the category’s early phases used batteries that were disposable and not user-serviceable. Now, the category is predominately composed of rechargeable devices that allow users to purchase battery

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6 By “battery pack” we mean a battery cell or battery cells within an enclosure, which may include safety components, where the battery cells are not intended to be user serviceable or replaceable.
units and cartridges or tanks separately. The use of the 18650 battery in ENDS devices can be particularly problematic because:

- Many variants are capacity-centric and poorly-suited to ENDS discharge rates, leading to potential acute and long-term damage resulting in cell failure.
- There have been instances of counterfeit cells and scavenging/re-labeling of cells from used computer battery packs. This issue principally arises with general-use cells in the 18650 form factor.
- Protection devices built into “protected” cells can trip when exposed to ENDS discharge currents, leading to the use of unprotected cells.
- Loose batteries in consumers’ pockets, purses or luggage can be short-circuited by keys, coins or other metal objects, causing burns or other adverse outcomes.
- Atomizer heater element resistance and battery cell discharge capability must match; the probability of a typical consumer achieving this match is unlikely in the absence of knowledge of electrical theory.

III. FDA’s Premarket Product Pathways Should Provide Accelerated Review Processes so That Innovations and Enhancements in Battery Safety can be Rapidly Incorporated into ENDS Products

FDA’s premarket product pathways should facilitate an accelerated review and authorization of the iterative and incremental improvements to the electronic safety of ENDS without requiring such changes to undergo a full Premarket Tobacco Application (PMTA) review process. By taking this approach, FDA would address the present dilemma in which manufacturers of ENDS products cannot make such iterative and incremental improvements unless they submit a PMTA for each change to the product.

Specifically, FDA should take immediate action to simplify and streamline the PMTA process for applications for ENDS products focused solely on electrical safety by issuing a market order if the applicant submits evidence of conformance with consensus safety requirements and can demonstrate that the proposed changes do not impact the aerosol generated by the ENDS product.

FDA should also initiate a process to establish baseline performance standards via Section 907(a)(3) for ENDS electronic safety that would apply to all marketed ENDS products. Such a standard could also serve as the basis for an abbreviated or alternative marketing authorization pathway to satisfy the statutory PMTA requirements. FDA has the ability to request data from manufacturers to assist in creating these performance standards. If a manufacturer wishes to seek marketing authorization for a battery with different or additional attributes not covered by applicable standards, FDA could utilize an abbreviated PMTA process to consider the novel attributes. Congress clearly intended that different levels of regulation would be appropriate for

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8 Family Smoking Prevention and Tobacco Control Act (FSPTCA), Section 907.
different categories of tobacco products\(^9\) and FDA is sufficiently equipped to implement such accelerated or modified PMTA pathways for ENDS products. Indeed, FDA has similarly utilized this statutory authority in the past to develop flexible approval policies, modified processes, and non-enforcement policies for certain classes of drugs, medical devices, and other products. We urge FDA to adopt a similar approach to its review of proposed changes to batteries in ENDS devices.

**Conclusion**

We appreciate the opportunity to submit these comments and urge FDA to consider them as it continues its work in this area. The April workshop initiated collaborative, productive discussions, and we encourage the agency to hold additional workshops to continue gathering relevant information. In the meantime, I can be reached at 804-335-2879 if you have any questions.

Sincerely,

[Signature]

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\(^9\) For example, FSPTCA Section 907(a)(I)(A), establishes special rules for cigarettes, Section 907(e) specifically addresses menthol cigarettes, and Section 907(f) specifically addresses dissolvable tobacco products. Additionally, Section 911 establishes a separate regime for “modified risk” tobacco products.