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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, N.W.
Suite CC-5610 (Annex J)
Washington, D.C. 20580

Re: Electronic Cigarettes: Paperwork Comment, FTC File No. P144504

Dear Sir or Madam:

RAI Services Company ("RAIS"), on its own behalf and on behalf of R. J. Reynolds Vapor Company ("RJRVC"),¹ submits the following comments regarding proposed information requests that the Federal Trade Commission ("FTC" or "Agency") is considering sending to "marketers of electronic cigarettes," as set forth in the notice published on October 27, 2015, in the Federal Register.

Summary of RAIS' Comments

RAIS understands that the FTC is contemplating collecting information and preparing a report regarding the current "electronic cigarette market" and is requesting comments regarding the utility, scope, and burdens imposed on respondents of this proposed effort. These comments provide an overview of the current electronic cigarette industry and respond to the specific questions posed by the Agency. RAIS notes, however, that the FTC has not set forth in the notice or in the accompanying press release the intended use of this report. This lack of specificity hampers RAIS' ability to comment on some of the specific questions posed by Agency since the intended use of data would provide the best guide as to determining the most appropriate method for reporting information.

¹ RAIS is a wholly-owned subsidiary of Reynolds American Inc. ("RAI"), which bears primary responsibility for coordinating implementation of laws and regulations potentially impacting RAI's regulated operating companies, including R.J. Reynolds Vapor Company.

Although the FTC notice broadly refers to “electronic cigarettes,” the market for electronic cigarettes in this country can be generally divided into three product categories: disposable e-cigarettes, rechargeable pre-filled cartridge e-cigarettes (such as VUSE, manufactured by RJRVC), and larger “tank” products that typically require consumers to place e-liquid into a vapor-generating device. There are numerous companies who participate in this market, and most appear focused on one of these three product categories. Marketing and sales practices vary by product and manufacturer, and adult consumer preferences among these product categories appear to be evolving.

The FTC notice states that the impetus for the effort to collect information on the electronic cigarette market is the “increasing prevalence of e-cigarettes.” Recent government data addresses adult prevalence and suggests that use of these products remains limited. Data collected by the U.S. Centers for Disease Control from the 2014 National Health Interview Survey suggest that 12.6% of adults who have smoked at least 100 cigarettes in their lifetime have tried an “electronic cigarette” and only 3.7% of adults consume e-cigarettes on a daily or “some day” basis.² Further, these data suggest that use of e-cigarettes by never smoking adults is relatively rare, 0.4%. RAIS believes that these data, and the limited use of these products that it suggests, is relevant to the Agency’s assessment of the need, scope, and timing for collecting the data it seeks.

Moreover, as the FTC is aware, the regulatory landscape regarding electronic cigarettes appears likely to change in the near future given the U.S. Food and Drug Administration’s determination that it has regulatory authority over these products that contain nicotine derived from tobacco pursuant to the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (“Tobacco Control Act”). *See* 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, 79 Fed. Reg. 23142 (Apr. 25, 2014). These regulations are in the final stages of review and could have a significant impact on the electronic cigarette market. That is particularly the case if, as reported, the grandfather date for electronic cigarettes is February 15, 2007,³ as most, if not all, of the electronic cigarette products now available were

² C. Schoenborn & R. Gindi, NCHS Data Brief No. 217, “Electronic Cigarette Use Among Adults: United States, 2014” (Oct. 2015). As the authors explain, use of e-cigarettes was determined by first describing an e-cigarette for the respondent (“The next questions are about electronic cigarettes, often called e-cigarettes. E-cigarettes look like regular cigarettes, but are battery-powered and produce vapor instead of smoke.”). The respondent was then asked, “Have you ever used an e-cigarette, even one time?” Those who said “yes” were referred to as having “ever tried an e-cigarette.” Adults who had ever used an e-cigarette, even one time, were then asked, “Do you now use e-cigarettes every day, some days, or not at all?” Current e-cigarette use includes respondents who reported using e-cigarettes every day or some days.

³ Section 910(a)(1) of the Tobacco Control Act defines the term “new tobacco product” as “(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States *as of February 15, 2007*; or (B) any modification . . . of a tobacco product where the modified product was commercially marketed in the United States *after February 15, 2007*.” 21 U.S.C. § 387j(a)(1) (emphases added). The italicized date, on which the definition of a “new tobacco product” turns, is referred to as the “grandfather date.”

not on the market in the U.S. at that time. For this further reason, RAIS believes that it is premature for the FTC to commence a three-year study that it estimates will impose significant financial and time burdens on respondents. In the alternative, RAIS suggests that the Agency defer the decision whether to collect this information pending clarification from FDA regarding the scope and impact of its deeming regulations pertaining to these products. To the extent that the FTC is disinclined to do so, RAIS suggests that, to the extent practical and appropriate, data collection conform to existing methods employed by the Agency for cigarettes and smokeless tobacco products. Those existing methods have been carefully developed and refined over the past several decades and provide guideposts to the efficient collection of sales and marketing data.

Overview of the Electronic Cigarette/Vapor Market

Electronic cigarettes first entered the American marketplace approximately in 2006-2007. These products, however, were not widely available until several years later. Since that time, the number of products on the market has proliferated and the product offerings have evolved and become differentiated. At present, the market for electronic cigarettes in this country can be divided into three distinct product categories: disposable e-cigarettes, rechargeable pre-filled cartridge e-cigarettes (such as VUSE),⁴ and larger capacity “tank” products typically designed to be filled/refilled with separately sold e-liquid containers. Regardless of format, these products generally operate in a similar mechanical manner; namely, the product uses a battery to heat a coil (referred to as an atomizer) which, when it is powered and comes in contact with e-liquid (typically, glycerin and/or propylene glycol, water, nicotine, and natural and/or artificial flavors) produces an aerosol (also referred to as vapor). Within this general framework, however, there are many differences in product design, construction, and performance.

Disposable e-cigarettes, as the name suggests, are single-use products intended to be discarded after depletion of the battery or e-liquid. Rechargeable pre-filled cartridge e-cigarettes, on the other hand, use a rechargeable battery and a cartridge that contains the e-liquid and atomizer. Users retain the rechargeable battery portion of the e-cigarette while discarding and replacing individual pre-filled cartridges as necessary. Finally, there are numerous “tank” products on the market that are designed to require the consumer to fill/refill e-liquid into a reservoir that includes an atomizer and attaches to a battery. As designed, these tank systems permit the consumer to combine product components made by different manufacturers.

The industry consists of numerous companies that sell each of these types of products, including each of the various components that are used in a tank system; namely e-liquids. However, it is difficult to quantify reliably the number of companies selling these various products in the U.S. market. The manner of sale of these products tends to vary with the product. Disposable e-cigarettes and rechargeable e-cigarettes along with their pre-filled cartridges are typically sold in retail stores that also sell conventional tobacco cigarettes and smokeless tobacco products, whereas “tank” products, including e-liquid containers, are frequently sold in retail

⁴ See “Fact Sheet, VUSE Digital Vapor Cigarette Construction and Safeguards” (rev. June 23, 2014), *available at* <http://rjrvapor.com/Pages/Media.aspx>.

stores, commonly referred to as “vape” shops, dedicated to those products. Moreover, many of these “vape” shops mix or compound the e-liquids sold there, transforming these retailers into manufacturers under the Tobacco Control Act. Many of these electronic cigarette products are also available for sale on the internet.

Responses to Specific Questions Posed by the FTC

A. Study Participation and Utility

The FTC intends to collect data for this report from five “large” companies and ten “small” companies over a period of three years. It does not indicate how or why it selected this number of companies to participate, how it defines either category, how it would choose among the companies it determines to be in either category, or whether their products, sales, or marketing activities are generalizable to others or the industry at large, or the actual purchases of adult consumers. These ambiguities are significant and limit RAIS’ ability to comment on the scope and utility of the information to be collected by the FTC.

To the extent an overarching goal of the Agency is to obtain data to characterize the sales and marketing activities of the electronic cigarette industry, which it correctly acknowledges is “quick-changing,” it is unclear whether it can do so with information from five “large” companies and ten “small” companies. This is particularly the case given the segmented nature of the market, as described above. In the first instance, the companies selected must correspond with the products being purchased by consumers. Further, companies in the different product categories may have different approaches to the sales and marketing of their products. Many companies making disposable e-cigarettes engage in limited marketing. Rechargeable non-refillable cartridge e-cigarettes, such as VUSE, are primarily sold to wholesalers who in turn sell them to traditional tobacco retail outlets such as convenience stores and gas stations. Refillable tank products are typically sold on the internet and in brick and mortar shops dedicated to those products. As a result, it is unlikely that the data the Agency obtains will be readily comparable or capable of simple synthesis. More importantly, if the data collected does not reasonably characterize the actual market, its utility will be limited.

An alternative approach to the selection of companies to participate in this reporting would be to identify the different types of market participants (*i.e.*, disposable e-cigarette, rechargeable non-refillable cartridge, and refillable tank system which includes separately sold e-liquid containers) and select respondents from those categories. This approach also presents less need for highly differentiated data on sales and marketing by product type since any particular company’s data is not necessarily reflective of the many other competitors in their product category.

B. Anticipated Scope of Data

Subject to the foregoing concerns regarding the timing of this report and identification of respondents, RAIS suggests that FTC's ongoing collection of marketing and sales data regarding cigarettes and smokeless tobacco provide reasonable and appropriate guideposts for the scope of data to be collected here. The Agency has several decades of experience collecting that data regarding cigarettes and smokeless tobacco sales and marketing expenditures. Moreover, the sales and marketing categories used for cigarettes and smokeless tobacco appear to conform to the anticipated scope of data to be collected for this report regarding electronic cigarettes/vapor products.

The Agency asks whether the marketing and sales data should be further differentiated by type of product, nicotine concentration, size, and method of sale. RAIS disfavors such further differentiation for several reasons. First, it is unclear that the Agency will be aided by information at this level of detail. Given that this detailed information will be obtained from relatively few companies who may or may not be engaged in similar product segments, it will be difficult to make comparisons between companies or reliably estimate how other companies not reporting allocate spending by these categories. In short, it is unclear that the information will have any practical utility. Notably, for cigarettes and smokeless tobacco where data is being obtained comprehensively from the largest manufacturers, the FTC currently only collects data for brand families, not each specific brand style. Second, it will render production of the requested data significantly more burdensome. Less detailed data, along the lines that is already obtained for other tobacco products, is sufficient for the Agency to obtain important information about products, sales and "give-aways," and marketing expenditures across a wide array of marketing activities. Third, were the FTC to publicize the data it obtains at that higher level of detail, it may inadvertently compromise its confidentiality. That could occur, for example, based on the report's ultimate description of the respondents and how they were selected, particularly given the limited number of respondents and segregation of market participants.

The Agency also requests comments on whether it should collect data segregated by the "flavor" of the product, or alternatively "categories of flavors." It further asks if it were to do so using "categories of flavors," how should the categories be defined. For the reasons stated above, RAIS believes that products should not be reported on the basis of flavors. Moreover, RAIS doubts that there is utility to attempting to differentiate the data based upon "flavor" of the e-cigarette or vapor product. First, characterization of flavors is a complicated, inherently subjective process (excepting perhaps menthol). As such, it is likely to result in sales data that are difficult to interpret since it is unlikely that such characterization can be done consistently across products. Second, this problem is not resolved by resorting to "categories of flavors," since such categories will also be subjectively defined and creating flavor categories will not itself clarify how to determine whether a particular product falls into a particular category. To the extent that the FTC nonetheless concludes that data should be segregated based on product flavor, the most straightforward way to obtain that information is to rely on brand style names and descriptions created by manufacturers to describe their own products. The FTC can then describe and summarize that information, if judged necessary or helpful. This approach also has

the benefit of relying on manufacturers' existing product shelf-keeping-units (i.e., SKUs), and thus enhancing information accuracy while minimizing burden. Further, providing information in this fashion should suffice for the Agency's purpose of having a general understanding of what products are sold and the marketing and distribution of those products.

The Agency also requests comments on how to account for sales of e-cigarettes that are sold with more than one cartridge, *i.e.*, whether the additional cartridges should be counted as part of the original sale or as "refills." For simplicity and clarity of the data, RAIS believes that the Agency should abide by the product configurations as sold to consumers. Relying on existing SKUs to distinguish between products will enable respondents to rely on existing records to produce data. Further, providing information in this fashion should suffice for the Agency's purpose of having a general understanding of what products are sold and the marketing and distribution of those products. Variance between product offerings can be described in the body of the report, if judged necessary or helpful.

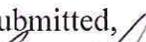
Finally, the Agency requests comments on whether the product sales data it seeks should be segregated on a state-by-state basis. As the Agency is aware, for products (such as VUSE) sold primarily through wholesalers, such data is not readily available because many wholesalers sell the products they purchase in more than one state. There is no efficient and reliable way to obtain state-level sales data. For this reason, as is currently done in the context of data submitted for cigarettes and smokeless tobacco, the FTC should not require respondents to segregate sales data (even assuming it is possible for some products), on a state-by-state basis. RAIS also questions what utility would be derived from state-level sales data and notes that the FTC does not explain why it would be useful.

C. Accuracy of Burden Estimates

The Agency estimates the burden on respondents of complying with the information requests in terms of hours and employee cost/hour. The FTC estimates that the average amount of time to respond to this request will be 200 hours in the first year, and 150 hours per year in each of the two subsequent years. The FTC further estimates that the hourly cost of compliance is \$100. The FTC does not describe how these estimates were calculated rendering it impossible to provide comments regarding those calculations. RAIS believes that neither estimate accurately reflects the burden imposed by the collection of the contemplated information.

RAIS has significant experience in compiling and reporting similar data to the FTC for cigarettes and smokeless tobacco. Notwithstanding that experience, compliance with those requests -- which are similar to that contemplated here -- typically requires more than twice the amount of time that is estimated for these requests. Numerous personnel are involved and the hourly costs of those personnel generally exceed \$100/hour when one factors in the overall cost of employee time. It is unclear whether the Agency estimate includes time that will inevitably be spent communicating directly with Agency staff to obtain information or clarification regarding these requests. Such further time can reasonably be anticipated, and thus should be accounted for in these burden estimates.

Of course, the amount of time (and the associated cost) required to comply with these requests will be directly related to the level of detail sought by the Agency. As such, any effort by the Agency to simplify these requests and to conform to existing processes and definitions would be important in reducing the compliance burdens. For this reason, RAIS strongly encourages the FTC to employ existing definitions of categories of information it captures, consistent with its data collection for cigarettes and smokeless tobacco. *See* FTC Cigarette Report for 2012 (2015), Appendix - 2012 Advertising and Promotional Expenditure Categories. Further, to the extent that information requests here will require narrative responses, the amount of time to respond will be significantly affected. RAIS encourages the FTC to minimize the requirements for such responses.

Respectfully submitted, 


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