



This document is scheduled to be published in the Federal Register on 11/02/2016 and available online at <https://federalregister.gov/d/2016-26486>, and on FDsys.gov

[Billing Code: 6750-01-S]

FEDERAL TRADE COMMISSION

Agency Information Collection Activities;

Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (“FTC” or “Commission”).

ACTION: Notice.

SUMMARY: The FTC is submitting the information collection requirements described below to the Office of Management and Budget (“OMB”) for review, as required by the Paperwork Reduction Act (“PRA”). The FTC is seeking public comments on proposed information requests to marketers of electronic cigarettes (“e-cigarettes”). The FTC proposes to issue compulsory process orders to up to 15 e-cigarette manufacturers, distributors, and marketers per year for information concerning, among other things, data on annual sales and marketing expenditures. The Commission intends to ask OMB for a three-year clearance to collect this information.

DATES: Comments on the proposed information requests must be received on or before [insert date 30 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the SUPPLEMENTARY INFORMATION section below. Write “Electronic Cigarettes: Paperwork Comment, FTC File No. P14504,” on your comment. File your comment online at <https://ftcpublic.commentworks.com/ftc/electroniccigarettespra2> by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the

following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Elizabeth Sanger or Rosemary Rosso, Division of Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission. Telephone: (202) 326-2757 (Sanger) or (202) 326-2174 (Rosso).

SUPPLEMENTARY INFORMATION:

I. Background

In the past few years, sales of e-cigarettes have grown rapidly in the United States.¹ These devices are available in both disposable and refillable models, in a range of nicotine strengths (including nicotine-free), and in a multitude of flavors. E-cigarettes are manufactured, distributed, and sold by a wide variety of industry members, ranging from large companies, including major U.S. tobacco companies, to small, single-location operators. They can be purchased at conventional retail stores, at “vape shops,” which are retail stores that primarily or exclusively sell e-cigarettes, and online.

For many years, the Commission has published reports on sales and marketing expenditures by the major cigarette and smokeless tobacco manufacturers. These data allow the agency to analyze industry sales and assess how industry members allocate their promotional activities and expenditures. The data also provide information to policymakers and public health researchers that, in many instances, is not available from other sources. Given their increasing prevalence, the Commission believes it is important and necessary for the agency to begin collecting information about e-cigarette sales and marketing activities. The Commission intends

¹ These products are most commonly referred to as e-cigarettes, but sometimes also are referenced as vape pens, personal vaporizers, e-hookah, and electronic nicotine delivery systems. This information collection would cover all such products, regardless of how they are referenced.

to publish a report with the data it obtains,² and to issue similar information requests regularly in order to track trends over time. The information will be sought using compulsory process under Section 6(b) of the Federal Trade Commission Act, 15 U.S.C. 46(b).

The Commission intends to issue information requests to up to 15 industry members, including larger and smaller entities, and will seek information about the different types of e-cigarette products marketed, certain characteristics of those products, and information about marketing expenditures for broad categories of media. While the data may not represent overall sales and marketing activities for the entire e-cigarette industry, the information provided should provide a valuable snapshot of the current e-cigarette market, including its major players. Because the number of separately incorporated companies affected by the Commission's requests will exceed nine entities, the Commission is seeking OMB clearance under the PRA before requesting any information from the industry members.³ On October 27, 2015, as required by the PRA, the FTC published a Federal Register Notice seeking comments from the public concerning the proposed collection of information from e-cigarette marketers. *See* 80 FR 65758 ("October 2015 Notice"). As discussed below, 37 comments were received.

Pursuant to the OMB regulations that implement the PRA (5 CFR Part 1320), the FTC is providing this second opportunity for public comment while requesting that the OMB grant the clearance for the proposed collection of information. All comments should be filed as prescribed in the Request for Comment part below, and must be received on or before [insert date 30 days after date of publication in the FEDERAL REGISTER].

² The report would not disclose any company-specific confidential data.

³ Under the PRA, 44 U.S.C. 3501–3521, federal agencies must obtain approval from OMB for each “collection of information” they conduct or sponsor if posed to ten or more entities within any twelve-month period. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). “Collection of information” means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c).

II. Public Comments

The FTC received 37 comments in response to the October 2015 Notice.⁴ Of these, 20 comments expressly supported and substantively addressed the proposed data collection. A joint comment favoring the proposal was submitted by the following public health organizations: American Academy of Pediatrics; the American Heart Association; Campaign for Tobacco-Free Kids; Tobacco Control Legal Consortium; and Truth Initiative (“Joint Public Health Comment”). Comments supporting the proposal also were received from three individual public health or public interest organizations.⁵ Favorable substantive comments were submitted by three government-related entities or individuals: National Association of Attorneys General Tobacco Committee (“NAAG”); the Oregon Public Health Division; and the Comptroller of the City of New York; and from three academic centers involved in public health and tobacco control issues.⁶ Ten individuals, many involved in local health education or tobacco control activities, filed individual comments supporting the data collection.⁷

Five comments were received from industry members: R.J. Reynolds Vapor Company and RAI Services Company (“Reynolds”); Altria Client Services Inc. and Nu Mark LLC (“Altria”); Rock River Manufacturing, the tobacco products manufacturing division of Ho-Chunk, Inc. (“Ho-Chunk”); (4) Fontem US, Inc. (“Fontem”), and (5) Logic Technology Development LLC (“Logic”). None of these comments expressly opposed the proposed data

⁴ See <https://www.ftc.gov/policy/public-comments/initiative-626>.

⁵ Comments by Campaign for Tobacco-Free Kids (“CTFK”); American Lung Association; and Truth In Advertising, Inc.

⁶ Comment by Georgia State University Tobacco Center of Regulatory Science (“Georgia State”); Comment by Glantz, et al., University of California, San Francisco Tobacco Center for Regulatory Science and Center for Tobacco Control Research and Education (“UCSF”); and Comment by Ribisl et al., University of North Carolina Gillings School of Global Public Health (“UNC”).

⁷ Comments by K. Miloski (Riverhead Community Awareness Program); L. Rotolo (TFAC); S. Hills; D. Moore (Tobacco Free Action Committee); S. Fischer; A. Zanatta (Jewish Community Center); K. Keenan (Roswell Park Cancer Institute), M. James (POW’R Against Tobacco); J. DiFranza; and T. Cain (Anderson Aconee Behavioral Health).

collection, although two companies questioned whether the data collection was premature given the then-pending FDA deeming regulation that, among other provisions, asserts regulatory authority over e-cigarettes and other tobacco products.⁸ Each industry comment made suggestions that it asserted would enhance the quality, utility, and clarity of the information to be collected and reduce the burden on the respondents.

The remaining 12 comments did not substantively address the proposed data collection.

A. *General Support for the Data Collection*

In its October 2015 Notice, the FTC sought comments regarding whether the proposed collection is necessary.⁹ Many of the comments stated that the data collection would provide important information, especially given the increased use of e-cigarettes by youth,¹⁰ and the limited availability of data on e-cigarette advertising and marketing from other sources.¹¹ The Joint Public Health Comment stated that the collected data could provide valuable information and insights into the e-cigarette market and be used as a basis for public policy decisions. The UNC comment stated that the data collection would enable public health professionals to better understand where e-cigarette advertising and marketing dollars are being spent, and to help develop specific interventions to prevent underage use. The UCSF comment stated that the reports would enable retrospective assessment of advocacy activities and policy changes.

A number of comments made favorable comparisons between the proposed collection of information on e-cigarette sales and marketing expenditures and the FTC's existing reports on cigarettes and smokeless tobacco, noting that the existing reports are widely used by public

⁸ FDA has since issued its final regulation: *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; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products* ("Deeming Regulation"), 81 FR 28974 (May 10, 2016).

⁹ See 80 FR 65758 at 65759.

¹⁰ See, e.g., Joint Public Health Comment; comments from CTFK; UCSF; and Oregon Public Health Division.

¹¹ See, e.g., Joint Public Health Comment; comments from CTFK; UNC; and Georgia State.

health professionals, researchers, policymakers, and government agencies.¹² These comments stated that expansion of data collection to e-cigarettes is needed to inform these same stakeholders about the nature and extent of e-cigarette advertising and marketing practices, and to allow them to monitor trends.¹³

The FTC believes that these information requests are in the public interest and essential to the agency's performance of its authority to investigate and report publicly on industry practices that affect the economic well-being of consumers. Consistent with the agency's information collection for cigarettes and smokeless tobacco products, the data will also provide important information for researchers and policymakers.

B. Utility of the Information Collection

The FTC's October 2015 Notice also sought comment on whether the proposed data collection is necessary for the proper performance of the functions of the FTC, including whether the information will be practically useful.¹⁴ The NAAG comment stated that the data collection would greatly facilitate state efforts to better understand and effectively regulate e-cigarettes. The Joint Public Health Comment and the Georgia State comment noted that the FTC's report would facilitate research into e-cigarette marketing because it would provide access to data that are otherwise unavailable from commercial sources, which tend to focus on larger companies and traditional distribution channels such as convenience stores. The UCSF comment states that scholarly research of e-cigarette marketing would be best served by reliable data, such as data collected directly from members of the e-cigarette market. Individual public health educators commented that a report on e-cigarette sales and marketing would facilitate their local and state

¹² See, e.g., Joint Public Health Comment; comments from Oregon Public Health Division; M. James; D. Moore; S. Fisher; S. Hills; and L. Rotolo.

¹³ See, e.g., comment from CTFK.

¹⁴ 80 FR 65758 at 65759.

health education work, which in turn informs evidence-based policymaking and regulatory action.¹⁵ One drug prevention specialist stated that a report on e-cigarette sales and marketing expenditures would also inform advocacy work and counter-marketing strategies to discourage youth and other vulnerable populations from using e-cigarettes.¹⁶

One industry member, Ho-Chunk, questioned whether the value of the proposed data collection could be outweighed by the risk that a negative public perception of e-cigarettes would damage the growth of the industry. The company expressed concern that the FTC's data collection could send a premature message that the industry is engaged in predatory marketing or that there are as-yet-unknown health and safety risks associated with the use of these products.

The Commission intends to use the data collection to provide useful baseline information (starting with 2015 data) concerning sales of the various e-cigarette products and allow the Commission to analyze how industry members allocate their promotional activities and expenditures across various media. The data also will provide researchers and policymakers with sales and marketing information that will assist their research and regulatory efforts. The Commission does not believe that the data collection itself will create any negative public perception of e-cigarettes or damage the growth of the industry. In particular, the proposal seeks sales and marketing expenditure data only and does not include an inquiry into any hypothetical predatory practices or health or safety information. In addition, the data collection here is very similar in content and methodology to studies that the Commission for many years has undertaken with respect to other markets, including cigarettes and smokeless tobacco products (OMB Control No. 3084-0134); alcoholic beverages (OMB Control No. 3084-0138); and food (OMB Control No. 3084-0139).

¹⁵ See, e.g., comments by L. Rotolo and M. James.

¹⁶ See comment by T. Cain.

C. *Suggestions to Improve the Information Collection*

In its October 2015 Notice, the FTC invited comments concerning ways to enhance the quality, utility, and clarity of the information to be collected.¹⁷ The FTC received substantive comments for enhancing its proposed data collection as follows: (1) expand the scope of the proposed data collection by collecting data from a broad cross-section of market participants and increasing the number of surveyed entities; (2) collect and report data on a state-by-state basis; (3) collect and report sales data that are segmented by product type, differentiates product characteristics such as flavors and nicotine strength, that include data on refills and cartridges, and that report sales data separately from product give-aways; and (4) collect and report broad categories of marketing expenditure data.

1. *Scope of the Data Collection*

The Commission's October 2015 Notice anticipated collecting and reporting data obtained from as many as 15 entities that would vary in size, in the number of products sold, and in the extent and variety of their advertising and marketing.¹⁸ A number of comments recommended that the Commission expand the scope of the data collection by including a broad cross-section of market participants, including distributors and entities whose products are sold in traditional retail stores (*e.g.*, convenience stores), as well as online sellers, and vape shops. To accomplish this goal, some commenters recommended that the Commission increase the number of entities from whom it would collect data.

a. Type of Market Participant. A wide range of commenters, including both industry and public health organizations and researchers, recommended that the Commission expand the scope of the proposed data collection by including a broad cross-section of market participants in

¹⁷ 80 FR 65758 at 65759.

¹⁸ *Id.* at 65760.

the entities surveyed through the data collection. Logic recommended that the FTC seek a broader cross-section of the market. Fontem commented that vape shops comprise a large percentage of the market, and noted that the data collection would not be meaningful if vape shops were not included. Altria also suggested that the FTC send data requests to a selection of vape shops. Reynolds recommended that the Commission differentiate the information requests by type of market participant, reasoning that such segmentation would present less need for highly differentiated sales and marketing data. The Joint Public Health Comment recommended that the FTC survey a selection of large companies, as well as a geographically dispersed selection of e-cigarette manufacturers, distributors, and retailers (including online sellers and vape shops) in order to get a cross-section of market participants. The UNC comment recommended that the proposed data collection differentiate the method of sale (distributors, online, retail) so that subsequent enforcement efforts can be tailored appropriately. Georgia State and one individual also recommended that the Commission differentiate by method of sale. Another individual recommended that the data requests segment market participants into two groups: those that sell only e-cigarette products and those that sell e-cigarettes and other tobacco products.

The Commission agrees that seeking data from a broad cross-section of the overall market, including distributors to conventional retail sellers, online sellers, and vape shops, would provide a fuller perspective on the overall e-cigarette market. However, the Commission was not able to find sufficient, reliable market data that would permit it to identify and select which smaller online sellers and vape shops should receive data requests. The available data from which the Commission could identify a sample of online sellers or vape shops are so limited and

insufficient that any separate samples of these sellers would at best provide anecdotal information.

In contrast, the available market data do permit a reliable sample of the largest e-cigarette marketers and some online sellers. The Commission believes that a sample of these companies will account for at least 80 percent of the conventional retail market and a sizable share of the online market. Thus, the data will provide useful information concerning at least this large subset of the overall market. At the same time, the Commission remains interested in collecting and reporting sales and marketing expenditure data from a broader cross-section of the market. Should more reliable market data become available, the Commission may seek OMB clearance to collect sales and marketing expenditure data for a broader cross-section of companies at such time, and would report on the data received.

b. Number of Entities Submitting Data. To capture data from a broad cross-section of market participants, several commenters recommended that the Commission collect data from more than 15 entities, the number identified in the October 2015 Notice. Altria recommended increasing the number beyond 15 entities given industry fragmentation and the increased market presence of vape shops. Reynolds questioned whether data collection from 15 entities would be sufficient to allow the FTC to characterize overall market sales and marketing activities. Logic stated that the proposed data collection was under-inclusive because too few companies would be required to report data. The Georgia State and Truth In Advertising comments stated that expanding the data collection beyond 15 entities would provide a fuller perspective and more accurate representation of the overall market. The Joint Public Health Comment also recommended that the FTC send data requests to more than 15 entities.

As discussed above, reliable data permitting the Commission to identify a representative sample of a broad cross-section of the market do not appear to be available at this time. As a result, the Commission does not believe it necessary to increase the number of entities from whom it will seek to collect and report data.

2. *State-By-State Data Collection*

The FTC's October 2015 Notice asked whether the agency should seek data on state-by-state sales of e-cigarettes.¹⁹ Altria recommended that the Commission consider conducting a state-by-state analysis given the highly fragmented nature of the overall market. Comments from public health organizations and research centers also supported state-by-state data collection for sales and, in some comments, also for marketing expenditures.²⁰ The UNC comment noted that reporting state-by-state data would help tobacco control professionals understand which states and regions have the greatest sales, and help them target their tobacco control efforts accordingly. The Oregon Public Health Division and Georgia State comments noted that state-by-state data would be useful in evaluating the impact of state and local regulatory efforts. Reynolds opposed state-by-state data collection, stating that such data were not readily available for e-cigarettes sold through distributors who sell such products in more than one state. Reynolds further stated that there are no efficient and reliable means to obtain state-by-state data.

Although the Commission agrees that state-by-state data collection could provide useful information, such data collection would significantly increase the complexity and burden of the data requests and might not be readily practical for some e-cigarette sellers. Thus, the Commission has decided against requesting approval for state-by-state data collection at this

¹⁹ 80 FR 65758 at 65759.

²⁰ See Joint Public Health Comment, recognizing that certain marketing expenditures made on a national level could not be reported on a state-by-state basis. See also comments from Oregon Public Health Division; UNC; Georgia State; UCSF; and T. Cain.

time. The Commission remains interested in this issue, however, and could request OMB clearance to collect state-by-state data in the future.

3. *Collection of Sales Data*

a. Type of Product. A number of commenters noted the wide variety of different e-cigarette products currently marketed. Reynolds noted that three general categories of e-cigarette products are currently available: (1) disposable products, (2) rechargeable and pre-filled cartridge products, and (3) “tank” products that require the user to put e-liquid into an aerosol-generating device. The Joint Public Health Comment recommended that the Commission require responders to report separately by product type.²¹ The UNC comment also supported separate reporting by product type, noting that separate reporting can be useful to track changes in popularity and use. Similarly, the UCSF comment supported separate reporting as a means to help evaluate how changes in sales of different products correspond to changes in use.

Reynolds recommended against differentiating by product type, noting that the different products generally could be categorized by the retail market where the products are sold, with conventional retail stores selling disposable and rechargeable products, and “vape stores” selling tank products. Reynolds preferred categorizing by type of marketer rather than type of product.

Given the wide variety of products available, the Commission believes that separate reporting by product type will be useful and important in tracking future developments in the e-cigarette market. Thus, the proposed data collection contemplates separate reporting across three categories: (1) non-refillable (*i.e.*, disposable) products; (2) refillable closed systems (*i.e.*, rechargeable and refillable cartridge products); and (3) refillable open systems (*i.e.*, “tank” systems).

²¹ Other commenters also supported separate reporting generally. *See* comments from CTFK; American Lung Ass’n; NAAG; L. Rotolo; and S. Fisher.

b. Differentiation by Flavors. Comments from public health organizations, research centers, and health educators recommended that the Commission seek sales data that are differentiated by their various characterizing flavors.²² The Joint Public Health Comment stated that flavors appear to be one of the reasons youth and adults try e-cigarettes. The CTFK comment stated that the available data suggest that flavors are a key reason youth try and use e-cigarettes, citing the 2013-2014 Population Assessment of Tobacco and Health (“PATH”) study, which showed that most youth smoked flavored e-cigarettes when they first tried the product and during the past month. The comment also cited data from the PATH study indicating that surveyed youth reported “comes in flavors that I like” as one of the reasons they used e-cigarettes. The Georgia State comment stated that data differentiated by flavors would help regulators and the public health community determine the role flavors play in patterns or reasons for use, perceptions of harm, and social norms.

Reynolds and Fontem opposed the collection of detailed flavor data. Fontem noted that there is no standardized method of reporting flavors across the industry, and both stated that characterizing flavors is subjective. Reynolds stated that the utility of seeking flavor data is not clear.

Given the potential importance of flavors for trial and use of e-cigarettes, especially among youth, the Commission will seek to collect data that differentiate among flavors. However, as discussed *infra* at section II.D.2, to reduce the burden, the proposed data collection will designate only three flavor categories, rather than requiring companies to report each flavor individually.

²² See Joint Public Health Comment, and comments from CTFK; American Lung Ass’n; NAAG; UNC; UCSF; Georgia State; M. James; and L. Rotolo.

c. Differentiation by Nicotine Strength. The comments from public health organizations, research centers, and NAAG supported the collection of data on nicotine content levels. The Georgia State comment indicated that research suggests nicotine levels are related to patterns or reasons for use. The CTFK comment stated that e-cigarettes contain highly variable amounts of nicotine, and there are no reliable data providing information about nicotine strength. The UNC comment indicated that information about nicotine strength could be valuable for determining equivalence to conventional tobacco products and for consideration of potential long-term health risks. The UCSF comment noted that nicotine content data could facilitate the testing of competing hypotheses as to the effect of nicotine regulation on use.

Fontem and Reynolds opposed collection of data concerning nicotine strength. Fontem commented that collection of nicotine content data would not be useful because there is no standardized method of reporting nicotine content across the industry. Reynolds also questioned whether nicotine content data would provide useful information.

The Commission believes that collection of data concerning nicotine strength will provide useful information that is not readily available from other sources. The agency does not believe that the lack of a standardized reporting method invalidates the utility of these data. The FTC will take into account the various comments received in the course of developing its report on the data collection.

d. Cartridges and Refills. Several commenters addressed the Commission's request for comments on the collection of data concerning refills, especially with regard to refillable products sold with more than one refill unit. E-cigarette products, other than disposable products, are often marketed to consumers with the device, battery, atomizer, and one or more refill units sold together in a single package. The Joint Public Health Comment stated that any

cartridge or liquid unit above one should be counted as a refill, regardless of whether it is packaged as part of the same stock keeping unit (“SKU”) or sold individually. Fontem stated that there is no consistency among marketers as to blister packs or refills that come in a single package. Thus, Fontem questioned whether gathering information on refills would yield meaningful information. The company recommended that if the Commission opted to track refills, that it simply track the total number of refills. Reynolds recommended that for products sold with more than one cartridge, the FTC should abide by the product configuration as sold to consumers, *i.e.*, allow companies to use the SKUs for reporting. Reynolds stated that relying on existing SKUs would allow responders to use existing records to produce data and, thus, would be simpler and clearer.

On balance, requiring companies to report the total number of refill units will provide a more accurate picture of e-cigarette sales. Thus, if an e-cigarette product is sold with more than one cartridge or e-liquid unit, each cartridge or unit above one should be reported as a refill. Likewise, each cartridge or e-liquid unit sold individually also would count as a refill. In addition, the Commission believes this approach is consistent with the approach it has taken with regard to the collection of sales data for other tobacco products. For example, if three pouches of smokeless tobacco are packaged together as a single unit for sale to consumers, the Commission’s compulsory process orders have required a responding company to report each pouch separately, for a total of three units.

e. Sales and Give-Aways. Comments from public health organizations and research centers generally supported the collection of data on both sales and give-aways and the reporting of these data separately.²³ CTFK noted that currently only limited data are available concerning

²³ See Joint Public Health Comment; see also comments from CTFK; UNC; UCSF; Georgia State; American Lung Ass’n; and NAAG.

market size and that current estimates do not differentiate between sales and give-aways.²⁴ The UNC comment stated that collecting sales and give-away data and reporting those data separately is important for evaluating which products are most frequently purchased, and the Georgia State comment noted that reporting the data separately more accurately reflects market transactions. The UCSF comment stated that give-aways are important to identify separately given their potential to reach youth under the age of 18.

The Commission agrees that data on sales and give-aways should be collected and reported separately given the distinct role each plays in the overall market. In addition, the agency collects and reports data on sales and give-aways separately in its data collection for cigarettes and smokeless tobacco products and, therefore, separate collection and reporting will be consistent with the approach taken for these other tobacco products.

4. *Collection of Marketing Data.*

A number of comments supported data collection for the various media specifically identified in the FTC's October 2015 Notice, as well as other marketing channels.²⁵ The NAAG comment stated that collection and reporting of broad categories of marketing expenditure data would be useful not only to the public but also to state officials who are assessing regulatory options and enforcement efforts.

²⁴ The CTFK comment and the Joint Public Health Comment also noted that collecting data on give-aways was especially important because at the time there were no national restrictions on free sampling. These comments noted that such restrictions would not take effect until FDA issued its final Deeming Regulation that, among other things, asserted jurisdiction over e-cigarettes and other tobacco products. As noted *supra* note 7, FDA has now issued its Deeming Regulation. As a result of this regulation, the national ban on the distribution of free samples will apply to all tobacco products. 90 FR 28974 at 29054; 21 CFR 1140.16(d). The prohibition on free sampling took effect on August 8, 2016. 90 FR 28974 at 28976.

²⁵ See, e.g., Joint Public Health Comment; comments from CTFK; Oregon Public Health Division; American Lung Ass'n; and NAAG.

The Joint Public Health Comment and the CTFK comment stated that it is important to collect marketing expenditures for television, radio, and other broadcast media, noting that unlike cigarettes and smokeless tobacco products, no statutory broadcast ban applies to e-cigarettes. Several comments specifically noted the importance of collecting and reporting data for marketing expenditures for media especially attractive to youth, such as point-of-sale advertising,²⁶ sponsorship of concerts and other events as well as sports teams or individual athletes or drivers,²⁷ and celebrity endorsers.²⁸ Several comments specifically identified product placement as a category where marketing expenditures should be collected and reported,²⁹ with the Joint Public Health Comment noting that expenditures for all forms of product placement should be collected, including product placement expenditures for broadcast media, movies, digital, and other media. The Georgia State comment supported detailed data collection for web-based and social media marketing expenditures, noting that availability of these data from commercial data sources is limited. Fontem recommended that the FTC include couponing as a category of marketing expenditures; the UCSF and Georgia State comments likewise identified coupons as well as other forms of price promotion as categories where the Commission should collect marketing expenditure data.

Reynolds recommended that the data collection focus on the marketing expenditure categories already used by the FTC in its data collection for cigarettes and smokeless tobacco products, noting that the Commission has decades of experience collecting those data. One individual commenter also recommended that the Commission seek and report the same

²⁶ See, e.g., Joint Public Health Comment.

²⁷ See, e.g., Joint Public Health Comment, comments from Oregon Public Health Division and NYC Office of the Comptroller.

²⁸ See, e.g., comments from Oregon Public Health Division and NYC Office of the Comptroller.

²⁹ See, e.g., Joint Public Health Comment, comments from CTFK and Oregon Public Health Division.

categories of marketing expenditure data tracked for cigarettes and smokeless tobacco products in order to facilitate comparisons.³⁰

The Commission agrees that collecting and reporting data for broad categories of marketing expenditures will be useful, including data concerning traditional and newer media, product placement, sponsorship, endorsements, and price promotions. The agency will seek to collect marketing data in categories that generally track those used for cigarettes and smokeless tobacco products, with two primary differences. First, the Commission will seek to collect and report data for marketing expenditures on broadcast media such as television and radio because, unlike cigarettes and smokeless tobacco products, no statute prohibits using these media to advertise and market e-cigarettes. Second, some of the categories have been updated to explicitly recognize newer forms of media now used for advertising and marketing, such as digital and social media.

D. Suggestions to Minimize the Burden of the Information Collection

The Commission's October 2015 Notice invited comments on ways to minimize the burden of the collection of information on entities required to respond to the data requests.³¹

1. Defer Data Collection Until Issuance of FDA Final Deeming Regulation

Reynolds and Fontem suggested that the Commission defer its data collection until after FDA issued its final Deeming Regulation. Reynolds noted that the final regulation would clarify the scope and impact of FDA's regulation of e-cigarettes. As noted above, FDA issued its final regulation on May 10, 2016. There is no overlap between FDA's regulation and the proposed data collection. Accordingly, it is not necessary to defer the data collection.

³⁰ Comment by J. DiFranza.

³¹ 80 FR 65758 at 65759.

2. *Categorize Product Flavors and Nicotine Strength*

As discussed above, the Commission plans to collect data concerning e-cigarette flavors and nicotine strength. To reduce the burden of reporting each individual flavor, the Joint Public Health comment and comments from CTFK and the American Lung Association recommended that companies report three categories of flavors: tobacco, menthol/mint, and other. The Joint Public Health comment stated that these three categories would most easily capture the breadth of flavors available, and make it easier for the industry and the FTC to count all the flavors. CTFK noted that categorizing in this manner would also eliminate the overlap that might result from more limited flavor categories. Comments from UCSF and NAAG, on the other hand, stated that the Commission should collect data on each individual flavor. Given the variety and number of different flavors, the Commission believes that classifying e-cigarettes into three categories of flavors – tobacco, menthol/mint, and other – will provide useful information while significantly reducing the burden on reporting companies, and will use these categories in the data collection, if approved.

The Joint Public Health Comment and the CTFK comment also indicated that reporting nicotine strength by categories might be sufficient and would reduce the reporting burden on responding entities. The UCSF comment, on the other hand, recommended that the Commission require companies to report each different nicotine strength. Categorizing nicotine strengths would require consultation with scientific authorities to determine the appropriate categories for reporting. In addition, reporting in categories could blur trends over time due to inherent imprecision. Thus, the Commission plans to require reporting for each individual nicotine strength sold by the reporting entity, rather than for categories. Once the Commission has these

data, it will consider how best to organize and discuss them in the course of developing its report.

3. *Narrow Scope of Data Requests by Requiring Less Specificity*

Reynolds and Fontem each recommended that the Commission require less detail in the data requests as a means of reducing the burden of responding, and suggested that the collection of certain information might not be useful. Fontem suggested that the Commission not seek information concerning product flavors, nicotine strength, or blister packs and refills. The company suggested that if the Commission did decide to collect flavor data, it require only two categories of information: tobacco and other. It also suggested that if the agency decided that some information about refills was needed, it simply track total number of refills sold. Reynolds suggested that the Commission model its requests on the information requests for cigarettes and smokeless tobacco products, and not require differentiation by type of product, nicotine concentration, size, method of sale, and flavors. If the Commission opted to seek information about flavors, Reynolds recommended that the agency request data based on brand style names and descriptions the product manufacturers created to describe their products. For the reasons discussed above, the Commission believes that the information collection should include information concerning flavors, nicotine strength, refill units, and other product characteristics. Collection of flavor information by broad categories, rather than individually, will reduce the burden on responding to the information requests.

4. *Limit Information Collection to Age Screening and Ad Content Review*

In its comment, Logic proposed that the Commission limit its information collection to data applicable to: (1) youth access and (2) illegal, inaccurate, or deceptive advertising claims about e-cigarettes. According to Logic, these two areas address the relevant societal issues for

information collection, consistent with the FTC's mandate to prevent unfair or deceptive business practices. Logic stated that collecting substantial data concerning sales and marketing expenditures would represent a substantial burden and, thus, suggested that the Commission confine the information sought to companies' age-screening mechanisms and to production of their advertising campaigns for review to ensure they are not making deceptive claims. The Commission disagrees with limiting the data collection to these two categories of information. Rather, broader information collection about sales and marketing expenditures is in the public interest, because it will allow the Commission to analyze sales and assess how industry members allocate their promotional activities and expenditures. For decades, the Commission has collected and reported information about sales and marketing expenditures for other tobacco products, as well as for other consumer products, and the e-cigarette information requests are consistent with the data collection and reporting for those products. Although the Commission agrees that preventing false and deceptive advertising is an important component of its consumer protection mission, law enforcement action against specific marketers, rather than information collection, is a better means of addressing potentially unfair or deceptive e-cigarette advertising.

E. Age-Screening Mechanisms

In its October 2015 Notice, the Commission anticipated that its data collection requests would include seeking information concerning efforts such as age-screening mechanisms to prevent youth from being exposed to advertising and promotion of e-cigarettes or from obtaining free product samples. One industry member, Logic, supported data collection regarding age-verification methods, stating that many online sellers use no age-verification methods at all while conventional retail stores require rigorous age-verification. The Joint Public Health comment, and comments from CTFK, Georgia State, UCSF, and one individual, also supported data

collection for this category, with Georgia State and UCSF also specifying age verification for online purchases. The Georgia State comment noted that data collection and reporting for this category would be useful to determine whether more stringent regulatory action was needed.

The Commission agrees that data concerning age-verification methods would be useful, and plans to collect and report data concerning age-screening mechanisms to prevent youth from being exposed to e-cigarette advertising and promotion or from obtaining free product samples.

F. Accuracy of Estimated Burden of the Information Collection

The Commission's October 2015 Notice invited comments on the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.³² The Commission estimated a per company average of 200 hours for each recipient of an information request for the first year, and a per company average of 150 hours for the remaining years. Thus, the total hours burden for 15 information requests was estimated to be 3,000 hours for the first year, and 2,250 for each of the subsequent two years, for a total of 7,500 hours. The Commission estimated that the total labor costs for 15 information requests to be \$300,000 for the first year, and \$225,000 for each of the subsequent two years, for a total of \$750,000. This estimate assumed an average \$100/hour wage, which is the same estimated wage average used in the Commission's recent request for reauthorization of information requests to cigarette and smokeless tobacco companies.

The comment from Reynolds asserted that the Commission had underestimated the total hours burden. The company stated that it usually takes it twice as long as the FTC's estimated time burden to compile information for similar data collections for cigarette and smokeless tobacco companies. Reynolds also stated that the FTC should include in its estimate the amount of time companies will need to communicate directly with Commission staff when seeking

³² 80 FR 65758 at 65759.

clarification regarding the data collection. Reynolds and Fontem commented that the FTC's labor cost estimate also underestimates the total burden costs, stating that an average wage of \$100/hour was too low. Neither company, however, provided an alternative figure or other information indicating what a more accurate hourly labor cost should be.

The Commission believes that its estimate burdens with respect to both average hours and labor costs are reasonable, especially in the absence of more specific information to calculate estimates that are more precise. However, out of an abundance of caution, the Commission has revised its burden estimate from that stated in the October 2015 Notice by increasing its estimated hours burden by 50 percent. As revised, the Commission calculates a per company average of 300 hours for the first year, and 225 hours for each of the two remaining years, resulting in a cumulative total of 11,250 hours for 15 information requests over three years. The Commission has not changed its average hourly cost estimate. The Commission's estimate is based on the assumption that the labor costs will include varying compensation levels among staff, management, and legal review, with most work performed by non-legal staff. In the absence of more precise data, the Commission believes that the same \$100/hour wage that it used in its recent application for reauthorization of information requests to cigarette and smokeless tobacco companies is appropriate here as well. As discussed *infra*, however, the total cost burden will increase due to the increase in the estimated hours burden.

G. Other Comments

The Joint Public Health Comment and the comments from CTFK and American Lung Association recommended that the Commission coordinate its data collection with FDA. The American Lung Association stated that coordination might be mutually beneficial for both agencies, and CTFK indicated that coordination might help assure consistency in measures.

Altria also encouraged the Commission to consider how it would interact with FDA once the Deeming Regulation was issued. The FTC staff and FDA staff already have a long tradition of working together on tobacco issues and the many other areas where the two agencies share jurisdiction. The FTC staff expects that tradition will continue. To the extent that coordination is required for specific issues concerning the proposed information collection, the agencies already have processes and procedures in place to address those issues.

The Georgia State comment recommended that the FTC require detailed brand-specific information, noting that the Commission's reports for cigarettes and smokeless tobacco products report aggregated rather than brand-specific data. The UCSF comment also recommended that the Commission collect and report brand-specific data. The Commission's compulsory process orders to surveyed companies will collect brand-specific data. However, because Section 6(f) of the FTC Act, 15 U.S.C. 46(f), protects confidential commercial information that is submitted to the Commission, the agency cannot publicly identify sales and marketing data for particular brands or companies that is not already public. Thus, the Commission's report on the data collection will provide aggregated rather than brand-specific data.

Commenters also recommended that the Commission seek more detailed differentiation of certain marketing expenditure data. The Joint Public Health Comment recommended that the Commission obtain data concerning the demographic composition of social media networks. The UCSF comment suggested collecting data regarding the amounts spent for different population subgroups, specific information concerning the time when marketing activities occurred, and requiring each responding company to identify its top three outlets and top three marketing programs within each media category. The added detail would significantly increase the complexity and burden of responding to the information requests. In addition, as indicated

above, the Commission cannot publicly identify sales and marketing data on particular brands or companies and, thus, would not be able to include the specific data in its report. Thus, the Commission will not seek to include these data in the proposed information requests.

The Georgia State comment recommended that the Commission collect data on e-cigarette device specifications and capabilities. The comment indicated that this information would permit assessment of product differences concerning characteristics such as nicotine delivery, patterns of use, and puff topography. Collection of these data, however, is beyond the scope of the information requests' purpose.

Fontem's comment recommended that the Commission review e-cigarettes as smoking cessation devices and that it expand the information requests in order to collect data on other smoking cessation products, such as nicotine patches. This suggestion is beyond the scope of the proposed information collection, which concerns sales and marketing data for e-cigarette products, not products intended to treat nicotine addiction, which is the intended use for smoking cessation products. Whether any product is approved for use as a smoking cessation product is a question within the jurisdiction of FDA, not the FTC.

As noted earlier, the FTC received twelve comments that did not address the proposed data collection. One individual raised concerns that some e-cigarette marketers were making false claims that the products were effective for smoking cessation, and four individuals indicated that e-cigarettes helped with smoking cessation. Three individuals called for regulation of e-cigarettes, which FDA's recent issuance of its Deeming Regulation accomplishes. One individual stated that e-cigarettes should not be available to persons under the age of 18. FDA's Deeming Regulation prohibits the sale (both in-person and online) of e-cigarettes and other

tobacco products to persons under the age of 18.³³ One individual commented that e-cigarette advertisements seem to be targeted to youth. One individual commented that the FTC should consider that a substantial portion of the e-cigarette market is for cannabis e-cigarette products rather than tobacco. Finally, one commenter asked the FTC to keep public health at the forefront of its decision-making.

III. Information Requests to the E-Cigarette Industry

The Commission proposes to send information requests to the ultimate U.S. parent entities of up to 15 e-cigarette marketers in the United States. These companies will vary in size, the number of products sold, and in the extent and variety of their advertising and marketing activities, and will include the largest marketers of e-cigarettes. As noted above, based on available market data, the Commission estimates its sample will account for more than 80 percent of the conventional retail market and a sizable portion of the online market.

The proposed information requests will seek sales data about the types and variety of e-cigarette products sold. The sales information will be reported under three broad categories: (1) non-refillable (*i.e.*, disposable) products; (2) refillable closed systems (*i.e.*, rechargeable and pre-filled cartridge products); and (3) refillable open systems (*i.e.*, “tank” systems). Within these three categories, companies will report data differentiated by the strength of nicotine content and three categories of flavors: tobacco, menthol/mint, and other. Data will be reported separately for sales and give-aways. The information requests will collect data for both unit sales as well as by net sales revenues. Data on net sales revenues will be reported by flavor only.

The information requests also will seek information and data concerning advertising and marketing activities and expenditures in a broad variety of media categories, including: (1) radio, television, and print advertising; (2) website, digital, and social media marketing; (3) product

³³ 90 FR at 28974 at 29103; 21 CFR 1140.14. This provision took effect on August 8, 2016.

placement; (4) endorsements, including celebrity endorsements; (5) sponsorship of concerts and other events and as well as of sports teams or individual athletes such as racing car drivers; (6) distribution of free samples; and (7) price promotions, including couponing programs. These expenditure categories generally track those used by the FTC in its data collections for cigarettes and smokeless tobacco products, with two exceptions. First, the proposed information requests will seek data concerning television and radio expenditures, since e-cigarette advertising is not subject to statutory broadcast media prohibitions. In addition, the media categories have been updated to provide more differentiation among online and digital advertising media.

The proposed information requests also will include information about company policies pertaining to age-screening mechanisms to prevent youth from being exposed to e-cigarette advertising and promotion or from obtaining free samples of e-cigarettes.

IV. Burden Estimates and Confidentiality

A. Estimated Hours Burden: 11,250 Hours

FTC staff's estimate of the hours burden is based on the time that would be required to respond to the Commission's information requests. The FTC currently anticipates sending information requests to as many as 15 e-cigarette companies each year. Because the Commission anticipates that these companies will vary in size, in the number of products they sell, and in the extent and variety of their advertising and promotion, and given the currently evolving nature of the e-cigarette industry, FTC staff has not calculated separate burden estimates for large and small companies, as is traditionally the case for the Commission's cigarette and smokeless tobacco information requests. For example, an e-cigarette marketer with a large volume of sales but a relatively small product line could potentially require fewer resources to respond to the Commission's information request than a marketer with lower overall

sales but a substantially larger product line that offers consumers a greater range of flavor and nicotine options. Rather than account for each potential permutation of factors, FTC staff has calculated a per company average at the upper limit of this potential range. Some companies likely will require less time to compile their responses.

The Commission anticipates that even if it provides models for the Excel datafiles the companies will be required to submit, recipients of its information requests will need substantial time to prepare a response the first time. Once an e-cigarette marketer has prepared its first response to a Commission information request, however, it will need less time in subsequent years to prepare its reports because it will know what information it will be required to produce, and will already have a template for its submission.

Accordingly, as an approximation, FTC staff assumes a per company average of 300 hours for each recipient of the Commission's information requests the first year they have to comply with the Commission's information request. Staff anticipates that in subsequent years, the per company average will be 225 hours. Thus, the overall estimated burden for 15 recipients of the information requests is 4,500 hours for the first year and 3,375 hours for each of the two subsequent years, or a total of 11,250 hours. Thus, the average yearly burden, over the course of a prospective three-year clearance, is 3,750 hours, or 250 hours per recipient (large and small). These estimates include any time spent by separately incorporated subsidiaries and other entities affiliated with the ultimate parent company that has received the information request.

B. Estimated cost burden: \$1,125,000

Commission staff cannot calculate with precision the labor costs associated with these data requests, as they entail varying compensation levels of management and/or support staff among companies of different sizes. FTC staff assumes that computer analysts and other non-

legal staff will perform most of the work involved in responding to the information requests, although legal personnel will likely be involved in reviewing the actual submission to the Commission. FTC staff believes that the same \$100 per hour wage that it used in its recent request for reauthorization of information requests to the major cigarette and smokeless tobacco manufacturers is appropriate here also for the combined efforts of these individuals. Using this figure, FTC staff's best estimate for the total labor costs for 15 information requests is \$450,000 (4,500 hours x \$100 per hour) for the first year and \$337,000 for the two subsequent years (3,375 hours x \$100 per hour x 2), for a total of \$1,125,000 over the entire three-year period. The annualized labor cost per respondent will average approximately \$25,000.

Staff believes that the capital or other non-labor costs associated with the information requests are minimal. Although the information requests may necessitate that industry members maintain the requested information provided to the Commission, they should already have in place the means to compile and maintain business records.

C. Confidentiality

Section 6(f) of the FTC Act, 15 U.S.C. 46(f), bars the Commission from publicly disclosing trade secrets or confidential commercial or financial information it receives from persons pursuant to, among other methods, special orders authorized by Section 6(b) of the FTC Act. Such information also would be exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(4). Moreover, under Section 21(c) of the FTC Act, 15 U.S.C. 57b-2(c), a submitter who designates a submission as confidential is entitled to ten days' advance notice of any anticipated public disclosure by the Commission, assuming that the Commission has determined that the information does not constitute Section 6(f) material. Although materials covered under one or more of these various sections are protected by stringent confidentiality

constraints, the FTC Act and the Commission's rules authorize disclosure in limited circumstances (*e.g.*, official requests by Congress, requests from other agencies for law enforcement purposes, and administrative or judicial proceedings). Even in those limited contexts, however, the Commission's rules may afford protections to the submitter, such as advance notice to seek a protective order in litigation. *See* 15 U.S.C. 57b-2; 16 CFR 4.9-4.11.

Finally, the information presented in the report will not reveal company-specific data, except data that are public. *See* 15 U.S.C. 57b-2(d)(1)(B). Rather, the Commission anticipates providing information on an anonymous or aggregated basis, in a manner sufficient to protect individual companies' confidential information, to provide a factual summary of e-cigarette industry marketing activities and sales.

V. Instructions for Submitting Comments

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [insert date 30 days from FEDERAL REGISTER date of publication]. Write "Electronic Cigarettes: Paperwork Comment, FTC File No. P114504" on your comment. Your comment – including your name and your state – will be placed on the public record of this proceeding, including to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card

number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which is . . . privileged or confidential” as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c).³⁴ Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/electroniccigarettespra2>, by following the instructions on the web-based form. When this Notice appears at <http://www.regulations.gov/#!/home>, you also may file a comment through that website.

If you file your comment on paper, write “Electronic Cigarettes: Paperwork Comment, FTC File No. P114504” on your comment and on the envelope. You can mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400

³⁴ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

7th Street, SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [insert date 30 days from FEDERAL REGISTER date of publication]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <http://www.ftc.gov/ftc/privacy.htm>.

Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street, NW, Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395-5806.

David C. Shonka
Acting General Counsel.
[FR Doc. 2016-26486 Filed: 11/1/2016 8:45 am; Publication Date: 11/2/2016]