[Billing Code: 6750-01-S]

FEDERAL TRADE COMMISSION

Agency Information Collection Activities;

Proposed Collection; Comment Request

AGENCY:

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) 326-7726 (Sanger) or (202) 326-2174 (Rosso).

SUPPLEMENTARY INFORMATION:

I. Background

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).

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*, MC /Linkm2(s)-m2(s)-m2(s)-m2(s)p

collection, although two companies questioned whether the data collection was premature giv the then-pending FDA deeming regulation that, among other provisions, would grant FDA 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.

health professionals, researchers, policymakers, and government agencies.[12] These comments stated that expansion of data collection to cigarettes is needed to inform these same stakeholders about the nature and extent of cigarette

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

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, differentiate 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 ecigarette 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 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 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

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 by state-by-state sales of e-cigarettes.[19] Altria recommended that the Commission consider conducting a state-by-state analysis -104(t)-2(he)4(6(s)(o)-4((T6(s)a co(e.)-4(04 Tc a)4(o14(et)-6(d)-4(o)-4(f004 T

[illegible]

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 pour 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 market 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.

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 TFK 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 3(e)4(c-1 0 Td]TJ3)3(oduc)4]TJ,(e)

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 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 and, thus, would be sim04 Tw -vid sed 5( )]Tcsnxix.0 Tw [(R)-3.1(e9.11j 0.26 0 Td /MCID 0 >>BDC -1 55.85 Td9.11jb)-4

market size and that current estimates do not differentiate between sales and giveaways.[24] The UNC comment stated that collecting sales and giveaway data and reporting the data separately isy-

The Joint Public Healt

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 generally. The Commission 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, statute does not prohibit persons using these media to advertise and ma2(a)4(t)-2(o)](h(t)-2(,0.0)]TJ 3.4-0 Td (os)Tj -0.004 Tc 0.03d ( )Tj 34(r)-1(ci)-16(g)6(a

2. Categorize Product Flavors and Nicotine Strength

As discussed above, the Commission plans to collect data concerning 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 resu aucCh32( )-

data, it

information collection

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 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 is 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 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 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

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 request's 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 two comments that did not address the proposed data collection. One individual raised concerns that some e-

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

constraints, the FTC Act and the Commission’s rules authorize disclosur

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, j EM

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