MEMORANDUM

TO: Docket FDA-2014-N-0189

FROM: Office of Regulations, Center for Tobacco Products, FDA

DATE: August 3, 2015

RE: Summary of Write-in Campaigns to Docket FDA-2014-N-0189

The United States Food and Drug Administration ("FDA" or "the agency"), Center for Tobacco Products, developed this memorandum to describe the write-in campaigns submitted as comments to the docket for the proposed rule, "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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (Docket Number FDA-2014-N-0189). The proposed rule, which was issued in the *Federal Register* on April 25, 2014, would deem products meeting the statutory definition of "tobacco product," except accessories of a proposed deemed tobacco product, to be subject to Chapter IX of the FD&C Act. (79 FR 23142) FDA also proposed requirements for minimum age of sale and the display of health warnings, and vending machine restrictions.

Members of industry, the public health community, government entities, and individuals submitted over 135,000 comments on the proposed rule. A large share of these comments was submitted as part of a write-in campaign ("write-in campaign submissions").[1] Comments to the docket, including write-in campaign submissions, were submitted in hard-copy via mail or hand delivery ("paper-based"), or electronically, through the Federal eRulemaking Portal at http://www.regulations.gov ("web-based").

When FDA receives paper-based write-in campaign submissions, the agency's practice is to assign a single comment identification number to the write-in campaign, to post one sample submission to that comment identification number, and to indicate the number of paper-based submissions in the title. The descriptive text for the comment entry also indicates that the entry is for a write-in campaign, rather than a single submission (e.g., "Write-in Campaign 1").

Section A of this memorandum describes each of the 14 write-in campaigns that are identified as paper-based submissions in the Federal eRulemaking Portal. In the description for each, we

[1] For purposes of this memorandum, we define "write-in campaign" to mean a group of submissions that are comprised of form letters that share identical text.

include the number of paper-based submissions in the campaign.[2] We also include separately the number of web-based submissions that appear to be submitted as part of the same campaign.

Web-based write-in campaign submissions are posted individually in the Federal eRulemaking Portal, rather than by campaign.[3] Thus, there may be hundreds of comment identification numbers associated with the same write-in campaign, and web-based form letters cannot be identified as a single campaign in the Federal eRulemaking Portal. We identified 57 write-in campaigns among the web-based submissions. We describe each in section B of the memorandum, and provide a comment identification number as a sample submission for each write-in campaign.[4]

All comments submitted to the docket are considered by FDA, regardless of whether they are posted on www.regulations.gov or whether they are identified as being part of a given write-in campaign. Furthermore, the public may view all comments that are not confidential by going to the FDA Docket's Management Reading room located at Room 1061, 5630 Fishers Lane, Rockville Maryland, 20852.

A. PAPER-BASED WRITE-IN CAMPAIGNS

The following are descriptions of the 14 paper-based write-in campaigns[5] submitted to this docket.

- *Write-in Campaign 1* (FDA-2014-N-0189-4587): This campaign includes approximately 155 comments from individual consumers, requesting an extension of the comment period to 180 days, to allow all stakeholders the opportunity to submit comments. The comments state the authors' firm belief that their lives were saved by electronic cigarettes. Aside from these paper-based submissions, we identified 2,546 web-based submissions that appear to be part of the same write-in campaign, but are not paper-based.

- *Write-in Campaign 2* (FDA-2014-N-0189-23922): This campaign includes approximately 19 comments submitted by brick-and-mortar retailers in support of exempting premium cigars from regulation, and opposing a minimum price requirement in the definition of "premium cigar." The comments argue that premarket review would be cost-prohibitive for many manufacturers, and that state laws protect against the sale of premium cigars to minors. This campaign also opposes a ban on the distribution of free

[2] Occasionally, paper-based submissions belonging to the same campaign are entered under two different comment identification numbers and appear to be separate campaigns. In this memo, we describe the two docketed "campaigns" as a single campaign, and provide the combined number of submissions.
[3] The Federal eRulemaking Portal automatically assigns each web-based submission a unique comment identification number.
[4] Only those web-based campaigns that contain five (5) or more form letter copies are included here.
[5] "Write-in Campaign 12" was entered in error and is not associated with a write-in campaign.

samples. Aside from these paper-based submissions, we identified 75 web-based submissions that appear to be part of the same write-in campaign.

- *Write-in Campaigns 3 & 11* (FDA-2014-N-0189-30771)[6]: This campaign includes approximately 1,745 comments in support of exempting premium cigars from regulation. The comments argue that premium cigars are not addictive or marketed to children, and that premarket review would result in the elimination of new products from the market. This campaign also opposes a ban on the distribution of free samples. Aside from these paper-based submissions, we identified 686 web-based submissions that appear to be part of the same campaign.

- *Write-in Campaign 4* (FDA-2014-N-0189-23923): This campaign includes approximately 68 comments requesting an extension of the comment period to at least 180 days. The comments argue that 75 days is insufficient for stakeholders to develop meaningful responses to the questions presented in the proposed rule. Aside from these paper-based submissions, we identified 107 web-based submissions that appear to be part of the same campaign.

- *Write-in Campaign 5* (FDA-2014-N-0189-82873): This campaign includes approximately 49 comments submitted by brick-and-mortar pipe tobacco retailers. The comments argue that regulation would harm their small businesses. Specifically, they oppose product sampling restrictions and pre-market review requirements, which they argue would eliminate special editions, seasonal blends, and in-store blends, and would decrease sales. The comments also argue that the requirement to register and submit product lists to FDA as a manufacturer would be burdensome for small businesses that blend pipe tobacco in their stores, and that existing retail policies already restrict youth access to tobacco. Aside from these paper-based submissions, we identified 433 web-based submissions that appear to be part of the same campaign.

- *Write-in Campaign 6* (FDA-2014-N-0189-82880): This campaign includes 2 comments submitted by individuals who support exempting premium cigars from regulation. The comments also request that the exemption be expanded to cover cigars made by the J.C. Newman Cigar Company. The comments express concern that regulation of these cigars would cause the closing of the J.C. Newman cigar factory, subsequently creating unemployment and the loss of cigar-making tradition in Tampa, Florida. Aside from these paper-based submissions, we identified 759 web-based submissions that appear to be part of the same campaign.

[6] Although entered with separate comment identification numbers, Campaigns 3 and 11 are identical, and we report them as a single campaign. This description represents the counts from both campaign numbers identified in www.regulations.gov.

- *Write-in Campaign 7* (FDA-2014-N-0189-82817): This campaign includes approximately 530 comments submitted by consumers that support exemption of premium cigars from regulation. The comments argue that regulation would infringe on the rights of cigar consumers and burden small businesses that manufacture and sell cigars. The comments also argue that Congress did not intend to regulate premium cigars when it passed the Family Smoking Prevention and Tobacco Control Act. Aside from these paper-based submissions, we identified 218 web-based submissions that appear to be part of the same campaign.

- *Write-in Campaign 8 & 9* (FDA-2014-N-0189-82876[7]): This campaign includes approximately 333 comments submitted by individuals in support of exempting premium cigars from regulation, and expanding the exemption to include cigars manufactured by the J.C. Newman Cigar Company. The comments argue that J.C. Newman cigars are made with vintage, hand-operated machines and are "indistinguishable from hand-rolled cigars." They further argue that regulation would force J.C. Newman to close the last cigar factory in Tampa, resulting in significant cultural and economic loss. Aside from these paper-based submissions, we identified 3991 web-based submissions that appear to be part of the same campaign.

- *Write-in Campaign 10* (FDA-2014-N-0189-35747): This campaign includes approximately 5 comments submitted by brick-and-mortar retail tobacconists in support of exemption of premium cigars from regulation. The comments argue that the Family Smoking Prevention and Tobacco Control Act is intended to decrease youth access to tobacco products, and that regulation of premium cigars would not further that goal, because youth access to premium cigars is already restricted. The comments further argue that regulation of premium cigars would place an undue burden on small businesses. Aside from these paper-based submissions, we identified 13 web-based submissions that appear to be part of the same campaign.

- *Write-in Campaign 13* (FDA-2014-N-0189-81428): This campaign includes approximately 100 comments from consumers in support of exempting premium cigars from regulation. The comments argue that regulation would infringe on the rights of consumers to enjoy premium cigars and to assemble with fellow cigar enthusiasts. The comments also argue that regulation would jeopardize small family businesses and threaten a tradition with historical and cultural significance. Aside from these paper-based submissions, we identified 13 web-based submissions that appear to be part of the same campaign.

[7] Although entered with separate comment identification numbers, Campaigns 8 and 9 are identical, and we report them as a single campaign. This description represents the counts from both campaign numbers identified in www.regulations.gov.

- *Write-In Campaign 14* (FDA-2014-N-0189-81427): This campaign includes approximately 401 comments from consumers in support of exempting premium cigars from regulation. The comments argue that regulation would burden the small businesses that manufacturer and sell premium cigars by restricting access to capital and increasing operating costs. The comments further argue that the result would be the loss of thousands of jobs in the United States, as well as the Dominican Republic, Nicaragua, and Honduras. Finally, the comments argue that Congress did not intend to regulate premium cigars when it passed the Family Smoking Prevention and Tobacco Control Act. We did not identify any web-based submissions to this campaign.

- *Tobacco Control Multiple Submitters* (FDA-2014-N-0189-82823): This campaign includes approximately 7,991 comments supporting regulation of all tobacco products, including cigars, electronic cigarettes, pipe tobacco, hookah tobacco, nicotine gels, and dissolvable nicotine products. The comments advocate for regulation of premium cigars and additional measures banning candy and fruit flavored tobacco products and restrictions on marketing of products that appeal to youth. We did not identify any web-based submissions to this campaign.

- *[dis]tastfulVA* (FDA-2014-N-0189-82840): This campaign includes approximately 2,116 comments. The comments are unique responses to the question "Why do you support a world without flavored tobacco?" We did not identify any web-based submissions to this campaign.

- *Evolvement* (FDA-2014-N-0189-62602): This campaign includes approximately 1,999 comments. The comments are unique responses to the question, "Why do you support a ban on flavored tobacco?" Aside from these paper-based submissions, we identified 99 web-based submissions that appear to be part of the same campaign.

B. WEB-BASED WRITE-IN CAMPAIGNS

Below is a description of the 57 web-based campaigns that were identified in a review of the electronic submissions. The docket number preceding each entry is the docket number of a single, sample submission in the campaign.

- FDA-2014-N-0189-11636: This campaign includes approximately 14,560 comments submitted by individuals in support of exempting premium cigars from FDA regulation. The comments also argue against including a $10 minimum price requirement in the definition of "premium cigar."

- FDA-2014-N-0189-43745: This campaign includes approximately 11,530 comments submitted by consumers who oppose regulation of premium cigars. Specifically, these comments argue that the premarket application requirements would be prohibitively

expensive for manufacturers of premium cigars, and that the February 2007 grandfather date is inappropriate.

- FDA-2014-N-0189-21938: This campaign includes approximately 9,493 comments from consumers of premium cigars that oppose including a $10 minimum price requirement in the definition of "premium cigar." They argue that a very small fraction of premium cigars are priced at or above $10, and that premium cigars are distinguished by their construction and composition.

- FDA-2014-N-0189-79477: This campaign includes approximately 4,320 signatures in support of the deeming rule, and advocating for regulation of all cigars, including premium cigars. The campaign also argues that FDA should restrict e-cigarette marketing that appeal to children and young adults, require childproof packaging for liquid nicotine, and ban flavors in cigars and e-cigarettes. The campaign was organized by the Campaign for Tobacco-Free Kids.

- FDA-2014-N-0189-15915: This campaign includes approximately 2,726 comments from consumers of premium cigars supporting exemption of premium cigars from regulation. The comments also oppose including a $10 minimum price requirement in the definition of "premium cigar".

- FDA-2014-N-0189-80172: This campaign includes approximately 2,616 comments from individuals that support regulation of all tobacco products, including premium cigars. The comments argue that cigar smoking causes death and disease, including COPD and cancer, and that youth under the age of 18 commonly smoke cigars. The comments also argue that FDA should require warning labels on all tobacco products, prohibit the sale of tobacco products to youth, and prevent companies from making tobacco products more harmful or more appealing to youth.

- FDA-2014-N-0189-79058: This campaign includes approximately 1,490 comments from individuals supporting exemption of premium cigars from regulation and advocating that the definition of "premium cigar" include all cigars manufactured by the J.C. Newman Company. The comments argue that this brand of cigars are made by hand-operated cigar machines and are indistinguishable from handmade cigars. The comments also argue that this brand of cigars is only marketed to adults.

- FDA-2014-N-0189-11584: This campaign includes approximately 1,346 comments from consumers opposing regulation of pipe tobacco and premium cigars. The comments argue that regulation may result in higher prices, or the removal of their favorite tobacco products from the market.

- FDA-2014-N-0189-9979: This campaign from premium cigar consumers includes approximately 1,280 comments opposing regulation of premium cigars. The comments

also argue that premium cigars are not marketed or sold to children, and that regulation of premium cigars is inconsistent with the intent underlying the Family Smoking Prevention and Tobacco Control Act.

- FDA-2014-N-0189-43659: This campaign includes approximately 1,060 comments opposing regulation of premium tobacco products. In particular, the comments argue that premarket application requirements and a February 2007 grandfather date would result in prohibitively high prices or removal of products from the market.

- FDA-2014-N-0189-10666: This campaign includes approximately 1,028 comments from individual consumers that address FDA's Paperwork Reduction Act statement. The commenters argue that FDA's estimates show that most e-cigarette and related products would not remain on the market after regulation, depriving consumers of choice. The commenters also argue that they were able to quit smoking traditional cigarettes with the help of e-cigarettes and vapor devices.

- FDA-2014-N-0189-58792: This campaign includes approximately 810 comments from consumers opposing regulation of premium cigars. The comments state that the pre-market application process would be cost prohibitive for many small manufacturers, and that the February 2007 grandfather date is arbitrary and would result in the removal of products that have been marketed and enjoyed by consumers for seven years.

- FDA-2014-N-0189-62680: This campaign includes approximately 570 comments from consumers opposing regulation of premium cigars. The comments argue that regulation would eliminate thousands of jobs in the United States and abroad. The comments also argue that the definition of premium cigars should not include a minimum price requirement, and that regulation of premium cigars would deprive millions of a favorite pastime.

- FDA-2014-N-0189-3086: This campaign includes approximately 524 comments requesting that FDA extend the comment period to 180 days. The comments argue that 75 days is insufficient time for the vaping industry and their customers to comment on the proposed rule.

- FDA-2014-N-0189-4580: This campaign includes approximately 377 comments from consumers in support of exempting premium cigars from regulation. The comments argue that the regulation would jeopardize small businesses and infringe on the rights of consumers to enjoy premium cigars and assemble with fellow cigar enthusiasts. The comments also argue that regulation is inconsistent with the intent underlying the Family Smoking Prevention and Tobacco Control Act.

- FDA-2014-N-0189-72872: This campaign includes approximately 196 comments from individuals supporting exemption of premium cigars from regulation and advocating that

the definition of "premium cigar" include all cigars manufactured by the J.C. Newman Company. The comments also argue that this brand of cigars is only marketed to adults.

- FDA-2014-N-0189-34809: This campaign includes approximately 168 comments from consumers supporting exemption of premium cigars from regulation and opposing the $10 minimum price requirement in the definition of "premium cigar." The comments argue that a minimum price requirement for premium cigars would cause confusion in the marketplace, particularly with respect to identical cigars that vary only in size, as larger versions may exceed the price requirement when smaller but otherwise identical versions would not.

- FDA-2014-N-0189-56827: This campaign includes approximately 164 comments submitted by cigar consumers in support of exempting premium cigars from regulation and opposing a minimum price requirement in the definition of "premium cigar." The comments argue that premarket review would be cost prohibitive for many manufacturers, particularly with respect to seasonal blends and special edition cigars. The comments also oppose a ban on the distribution of free samples of premium cigars and argue that premium cigars are not marketed or sold to youth.

- FDA-2014-N-0189-65561: This campaign includes approximately 118 comments submitted by consumers in opposition to the regulation of premium cigars. The comments argue that cigars are not consumed as a nicotine delivery device, and are not marketed or sold to youth. The comments further argue that FDA should focus on other health and safety issues.

- FDA-2014-N-0189-47661: This campaign includes approximately 97 comments submitted by individuals in support of the regulation of all tobacco products, and in opposition to an exemption for premium cigars. The comments argue that youth smoke cigars in large numbers, and that an exemption for any category of tobacco product would create a regulatory loophole that would allow for the sale and marketing of products that appeal to youth. The comments advocate for banning self-service displays, internet sales, and the sale of flavored tobacco products. The comments also argue for child-proof packaging of liquid nicotine and restrictions on advertising that appeals to minors.

- FDA-2014-N-0189-73583: This campaign includes approximately 74 comments submitted by electronic cigarette retailers in opposition to deeming e-cigarettes and vaping products subject to the Tobacco Control Act. The comments argue that premarket review requirements would be a burden to the industry that would potentially result in the loss of employment, and would not further public health. The comments support regulation of the e-cigarette industry, including enforcement authority against adulterated and misbranded products, establishment and enforcement of good manufacturing practices (GMPs) specific to the industry, registration and reporting requirements,

minimum age purchase, and child resistant packaging requirements, but oppose the proposed rule, and particularly the premarket requirements.

- FDA-2014-N-0189-53688: This campaign includes approximately 73 comments submitted by individuals who support regulation of all tobacco products, including e-cigarettes and cigars. The comments argue that cigar smoking is popular among youth, and that today, high school boys smoke cigars at the same rate as cigarettes. They also advocate for a ban on flavors for both cigars and e-cigarettes.

- FDA-2014-N-0189-3408: This campaign includes approximately 68 comments submitted by small businesses requesting that the comment period be extended to 180 days.

- FDA-2014-N-0189-75919: This campaign includes approximately 63 signatures to a petition supporting exemption of premium cigars from regulation and opposing a $10 price requirement in the definition of "premium cigar." The petition states that cigars are not marketed or sold to minors, and that regulation of premium cigars would threaten an artisan tradition with historical and cultural significance.

- FDA-2014-N-0189-64978: This campaign includes approximately 60 comments from premium cigar consumers supporting exemption of premium cigars from regulation. The comments argue that the regulation would infringe on the rights of consumers to enjoy premium cigars and to assemble with fellow cigar enthusiasts, and that regulation would jeopardize small businesses and threaten a tradition with historical and cultural significance. The comments also oppose banning the distribution of free samples, and argue that such a ban would eliminate the introduction of new products to the marketplace.

- FDA-2014-N-0189-62317: This campaign includes approximately 54 comments submitted by members of the American Academy of Pediatrics in support of regulation of all tobacco products, including electronic cigarettes, hookah, and cigars. The comments oppose an exemption for premium cigars, in part because cigars pose serious health risks and are becoming increasing popular among youth. The comments also advocate for bans on flavors and free samples, and regulations that require warning labels and child-resistant packaging requirements. Finally, the comments advocate for immediate enforcement, oppose a grace period, including the proposed two-year grace period for premarket requirements, and encourage FDA to publish a strong final rule as soon as possible.

- FDA-2014-N-0189-35317: This campaign includes approximately 51 comments submitted by health care providers in support of regulation, including registration and reporting requirements, premarket review, prohibition of free samples, and minimum age requirements. The comments also advocate for banning sweetened and candy-flavored

tobacco products and online sales, and requiring childproof packaging of electronic cigarette cartridges.

- FDA-2014-N-0189-42887: This campaign includes approximately 47 comments from consumers supporting an exemption for premium cigars and opposing a $10 price requirement in the definition of "premium cigar," which they argue would impose a discriminatory economic burden on cigar consumers. The comments also oppose premarket review and a ban on free samples, which they argue would eliminate special editions and seasonal blends, which are part of the tradition enjoyed by those who smoke cigars. The comments also argue that premium cigars are not marketed or sold to minors.

- FDA-2014-N-0189-11614: This campaign includes approximately 44 comments submitted by brick-and-mortar retail tobacconists in support of exempting premium cigars from regulation. The comments argue that a ban on free samples would decrease tobacconists' sales of premium cigars, as customers will not purchase seasonal blends, limited releases, or other new products if they are unable to try the products before purchase. The comments also argue that premium cigars are not marketed or sold to minors, and do not reflect the habitual use patterns of other tobacco products.

- FDA-2014-N-0189-70628: This campaign includes approximately 42 comments submitted by retail premium cigar tobacconists supporting exemption of premium cigars from regulation, in part because they believe regulation would jeopardize small businesses. The comments also oppose use of the term "characterizing flavor" in the definition of "premium cigar," because, they argue, the term is vague and subjective, and consequently retailers and manufacturers would be unable to determine whether or not a cigar would qualify for exemption.

- FDA-2014-N-0189-55800: This campaign includes approximately 39 comments submitted by health professionals in support of regulation of all tobacco products, including premium cigars, and advocating for stronger regulation than what is currently proposed. Among other things, the comments argue for banning the use of flavors, internet sales, celebrity endorsement, brand sponsorship, and other methods of marketing that appeal to youth. The comments also raise concerns about regulatory delay and the cost-benefit assessment in FDA's Regulatory Impact Analysis, including the accounting for "lost pleasure" from quitting smoking as a social cost.

- FDA-2014-N-0189-78060: This campaign includes approximately 35 comments submitted by e-liquid manufacturers and retailers. The comments stated that Congress did not intend for electronic cigarettes or its components to be banned by the Tobacco Control Act and suggested various regulatory frameworks for electronic cigarettes. Specifically, the comments suggested that the availability of electronic cigarettes would offer protection of public health; product standards and good manufacturing practices should be developed with industry and consumer protection advocates; a new grandfather

date should be applied to electronic cigarettes and electronic liquid products; and an alternative to Section 904(a)(1) compliance should be established for electronic liquid companies.

- FDA-2014-N-0189-58015: This campaign includes approximately 34 comments submitted by representatives of State Chapters of the American College of Cardiology. The comments support regulating premium cigars, banning the sale of flavored tobacco products, and restricting the marketing and sale of all tobacco products to minors, including internet sales. Further, the campaign proposes removing "lost pleasure" from the cost-benefit analysis, as tobacco users "…are either minors when they first [made] the decision or addicts, neither of whom by definition is able to make rational choices regarding their addictions."

- FDA-2014-N-0189-56584: This campaign includes approximately 31 comments submitted by public health professionals, in support of regulation of all tobacco products, including premium cigars, and advocating for stronger regulation than is proposed in the draft rule. The comments argue that youth smoke cigars in large numbers, and that an exemption for any category of tobacco product would create a regulatory loophole that would allow for the sale and marketing of products that appeal to youth. The comments also advocate banning sweet, kid-friendly flavors; self-service retail displays; and marketing techniques that appeal to youth, while encouraging FDA not to delay in effecting regulation.

- FDA-2014-N-0189-11400: This campaign includes approximately 28 comments from consumers supporting exemption of premium cigars from regulation and opposing the minimum price and minimum weight requirements in the definition of "premium cigar." The comments argue that premarket review would be cost-prohibitive for small manufacturers, limiting the availability of seasonal blends and special release cigar products. The comments also oppose banning the distribution of free samples, and argue that regulation would have an adverse effect on the economy. Finally, they argue that premium cigars are not marketed or sold to youth.

- FDA-2014-N-0189-78361: This campaign includes approximately 26 comments from consumers supporting exemption of premium cigars from regulation. They argue that regulation would restrict access to capital and increase operating costs, placing individual cigar businesses at risk and potentially eliminating thousands of jobs. The comments also argue that regulation would infringe on the rights of premium cigar consumers to assemble together and enjoy a variety of cigars, and that regulation is inconsistent with the intent underlying the Family Smoking Prevention and Tobacco Control Act.

- FDA-2014-N-0189-61165: This campaign includes approximately 26 comments submitted by local health departments in support of regulation of all tobacco products, including premium cigars. The comments argue that cigars are popular with youth, and

that there is no difference between the health effects of premium cigars and other tobacco products to justify an exemption, and that exemption would create a regulatory loophole, potentially resulting in a change of consumption patterns for premium cigars that resembles the consumption patterns for cigarettes and non-premium cigars. The comments advocate for a ban on flavors, including flavored e-cigarette and e-liquid products, and additional warning messages for the products that are only subject to the addictiveness warning label, graphic warning labels on all tobacco products, and child-resistant packaging for e-liquids.

- FDA-2014-N-0189-78970: This campaign includes approximately 23 comments submitted by tobacconists supporting exemption of premium cigars from regulation and opposing the exclusion of flavored cigar products from the definition of "premium cigar." The comments argue that regulation of premium cigars would place small tobacconist businesses at risk. The comments further argue that there is insufficient evidence to show that youth smoke premium cigars or that youth prefer flavored cigars.

- FDA-2014-N-0189-61801: This campaign includes approximately 20 comments submitted by individuals opposing the regulation of pipe tobacco. The comments argue that premarket review would be cost prohibitive for many manufacturers, particularly with respect to seasonal blends and special edition tobacco. The comments argue that pipe tobacco is different from the tobacco used in cigars and cigarettes, and should not be subject to the same regulations. The comments also argue that youth do not smoke pipes.

- FDA-2014-N-0189-31441: This campaign includes approximately 21 comments submitted by brick-and-mortar tobacconists opposing the minimum $10 price requirement in the definition of "premium cigar." They argue that the price of premium cigars is set by retailers, and common promotions that lower the price of a cigar from $10 or more to less than $10 would subject the retailer to liability. They also argue that FDA will need to reconsider the price minimum every two years, and changes would have to be made through notice and comment rulemaking, which would unnecessarily consume agency resources.

- FDA-2014-N-0189-42222: This campaign includes approximately 19 comments from small business owners opposing regulation of premium cigars. They argue that the cost of premarket review would limit availability of premium cigars, particularly seasonal blends, limited editions, and other unique products. The comments also oppose banning the distribution of free samples, and argue that regulation would limit the freedom of small business owners and cigar connoisseurs to enjoy a legal product.

- FDA-2014-N-0189-73037: This campaign includes approximately 17 comments from individuals supporting regulation of all tobacco products, including premium cigars. The comments argue that all tobacco products are harmful, and should be treated the same under the law – including components of e-cigarettes, such as flavor cartridges. The

comments also advocate for provisions that limit youth access to tobacco products, including minimum age requirements, health warning labels, and banning vending machine sales.

- FDA-2014-N-0189-71535: This campaign includes approximately 17 comments submitted by cigar manufacturers in support of exempting premium cigars from regulation and opposing a $10 price requirement, but otherwise agreeing with the proposed definition of "premium cigar." The comments argue that a $10 minimum would exclude the vast majority of cigars that otherwise meet the proposed definition, that a price minimum is not feasible in practice, in part because it ignores variability in price across sales channels and geographic regions, and that the selection of $10 appears to lack basis in public health. The comments advocate against premarket review, banning free samples, and the proposed required warning labels for cigars, which they argue are both disproportionately expensive for the premium cigar industry and also lack scientific basis. Finally, they argue that regulation of premium cigars would impact small businesses in the United States, and the economies of cigar-producing nations in Latin America.

- FDA-2014-N-0189-43235: This campaign includes approximately 16 comments submitted by brick-and-mortar retail tobacconists in support of exempting premium cigars from regulation. The comments argue that the pre-market review requirements that apply to mass-marketed products are prohibitively expensive for the small manufacturers that roll premium cigars by hand, and that regulation would eliminate seasonal blend and limited release cigars that are sold by small businesses, placing those businesses at economic risk. The comments also argue that there is no evidence to show that premium cigars present the same health risks as other tobacco products.

- FDA-2014-N-0189-80846: This campaign includes approximately 13 comments opposing regulation of electronic cigarettes. The comments argue that scientific and empirical evidence indicate that electronic cigarettes are less hazardous than traditional cigarettes, that they are consumed almost exclusively by smokers and ex-smokers who use them as an aid to quit smoking, and that FDA has intentionally misled the public about the safety of e-cigarettes. The comment text is over 110 pages long. There is inadequate space to summarize each argument in this memo format. The full text is available in the docket.

- FDA-2014-N-0189-10818: This campaign includes approximately 12 comments submitted by pediatricians supporting regulation of electronic cigarettes, and particularly with respect to provisions that limit youth access. The comments argue that youth do not use e-cigarettes to quit smoking, that youth who use e-cigarettes are more likely to become smokers of traditional cigarettes, and that some youth are not aware that flavored e-cigarettes contain nicotine, and may become addicted without intending to use a nicotine product. The comments argue that advertising of e-cigarettes should be subject

to the same restrictions as advertising of traditional cigarettes, and that the ban on flavors should also apply to e-cigarettes. Finally, they also advocate for child-proof containers to prevent accidental ingestion and toxic exposures.

- FDA-2014-N-0189-9606: This campaign includes approximately 12 comments from e-cigarette retailers and/or manufacturers addressing the information collection provisions of the deeming rule and opposing the regulation of e-cigarettes under the Tobacco Control Act. The comments argue that FDA underestimated the paperwork burdens that regulation would impose on the segment of the e-cigarette industry that manufactures and markets refillable vaping products and e-liquid refills, and that FDA should use discretionary enforcement powers to exempt these products from regulation. The comment text presents 25 pages of argument, which is available in the docket.

- FDA-2014-N-0189-56642: This campaign includes approximately 11 comments from individuals supporting regulation of tobacco products, and advocates for additional restrictions, including a ban on flavors, and banning internet sales and youth marketing.

- FDA-2014-N-0189-22126: This campaign includes approximately 11 comments from individuals opposing a $10 minimum price requirement in the definition of "premium cigar." They argue that the price requirement would result in the removal of lower-priced hand-rolled cigars from the market, and/or an increase in price to $10 or above. They further argue that regulation would result in the loss of thousands of jobs in the United States and smaller countries in Central and South America and the Caribbean, potentially causing the collapse of these smaller economies. They also oppose regulation of pipe tobacco, for the same reasons.

- FDA-2014-N-0189-57921: This campaign includes approximately 10 comments from individuals who request that the FDA extend the comment period to 180 days. The comments stated that 75 days is not sufficient for substantive comments to be developed to the many questions posed to stakeholders.

- FDA-2014-N-0189-73069: This campaign includes approximately 9 comments submitted by local governing bodies in support of regulation of all tobacco products, including premium cigars. They advocate for additional provisions, including bans on celebrity sponsorship and flavors; restrictions on advertising and internet sale of tobacco products; and requiring child-resistant packaging for e-liquids and consistent, minimum pack size for cigars of all sizes.

- FDA-2014-N-0189-67442: This campaign includes approximately 9 comments from individuals who oppose regulation of all cigars. They also argue that an exemption for premium cigars would be unfairly discriminatory, and request an exemption for cigars made in Tampa if the rule becomes final.

- FDA-2014-N-0189-79634: This campaign includes approximately 9 comments submitted by tobacconists, in support of exempting premium cigars from regulation, and opposing a definition of "premium cigar" that includes cigars with characterizing flavors.

- FDA-2014-N-0189-79415: This campaign includes approximately 8 comments submitted by manufacturers and importers in support of exempting premium cigars from regulation, or, in the alternative, in support of adopting a separate regulatory framework for premium cigars that reflects the recognized differences between and among different tobacco products. The comments concluded that Option 2 "more appropriately balance[s] the benefits and costs of regulation." The full text of the comment is 35 pages long, and is available in the docket.

- FDA-2014-N-0189-78933: This campaign includes approximately 8 comments submitted by individuals who oppose regulating cigars, and argue that regulation may result in the loss of the cigar industry in their city and create a black market for cigars.

- FDA-2014-N-0189-44943: This campaign includes approximately 7 comments from individuals who oppose regulation of any type of cigars by FDA.