August 8, 2014

VIA ELECTRONIC FILING – www.regulations.gov

Ms. Leslie Kux
Assistant Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 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 No. FDA—2014—N—0189

Dear Ms. Kux:

The National Association of Convenience Stores ("NACS") appreciates this opportunity to provide comments on the Food and Drug Administration's ("FDA" or the "Agency") proposed rule deeming tobacco products to be subject to the Food Drug and Cosmetic Act ("Proposed Rule" or the "Proposal").[1]

I. Overview

As further articulated in the following comments:

- NACS supports the proposed requirement that retailers be required to ensure that anyone who seeks to purchase e-cigarettes is at least 18 years of age. NACS has encouraged its members to adopt this approach as a best practice since before the Proposal was released.
- NACS opposes the proposed requirement that sellers of individual cigars place a warning statement adjacent to each cash register in a store. This is very valuable space for retailers. In addition, the final rule should clarify that (i) manufacturers (and not retailers) are responsible for developing and submitting rotation plans for product warning statements, and (ii) simply stating that tobacco products are available in a store does not constitute an "advertisement" for tobacco products.
- The final rule should be extended to cover online sales of newly deemed tobacco products, and should be enforced against Tribal retailers to the same extent that it is enforced against non-Tribal retailers.

[1] 79 Fed. Reg. 23142 (April 25, 2014).

- The distinction between "components" of tobacco products that would be subject to FDA authority and "accessories" of tobacco products that would not be subject to such authority should be clarified in the text of the final rule and not relegated to the preamble.
- The effective date for the deeming provisions and the minimum age and identification restrictions should be extended to 120 days from the final rule's publication date (rather than 30 days). This will provide retailers sufficient time to train their employees to comply with the new regulations.

II. Background

NACS is an international trade association composed of more than 2,200 retail member companies and more than 1,600 supplier companies doing business in nearly 50 countries. With approximately 149,000 stores in the United States, the convenience and petroleum retailing industry has become a fixture in American society and a critical component of the nation's economy. In 2013, the convenience store industry generated almost $700 billion in total sales, representing approximately 2.5% of United States GDP. Tobacco products accounted for approximately 37% of convenience stores' in-store sales in 2013.

While 49 of the top 50 convenience store companies in the United States are members of NACS, the majority of our members are small, independent operators. More than 70 percent of our total membership is composed of companies that operate ten stores or less, and more than 60 percent of our membership operates a single store.

NACS's underlying objective is to enable its members to sell legal products responsibly and be able to do so on a level playing field. Along those lines, NACS has devoted a substantial amount of time and resources to ensuring that convenience store operators are equipped to comply with federal, state, and local tobacco regulations. As a founding member of *We Card*, a non-profit organization providing tobacco retailers with multi-level training and educational products and services, NACS helps retailers prepare employees, set clear expectations, and provide continuous feedback in an effort to prevent underage access to tobacco.

III. Comments on the Proposal

A. Minimum Age of Purchase

NACS supports the proposed requirement that retailers be required to ensure that anyone who seeks to purchase a "deemed" tobacco product – including e-cigarettes – is at least 18 years of age. In March 2014, prior to the Proposal's release, NACS issued a formal position encouraging stores selling e-cigarettes to adopt, as a best practice, a policy of treating these products as age restricted and subjecting them to the same age-verification procedures as those applicable to tobacco products.[2]

This recent position regarding e-cigarette sales is only the latest of NACS's decades-long effort to keep tobacco products out of the hands of minors. NACS is a founding member of *We*

[2] *See* NACS Daily, "NACS Issues Position Relating to the Sale of E-Cigarettes," March 13, 2014, *available at* http://www.nacsonline.com/news/press_releases/2014/pages/pr031314.aspx#.U9-CY_ldWSp.

Card, a non-profit organization providing tobacco retailers with multi-level training and educational products and services. *We Card* helps retailers prepare employees, set clear expectations, and provide continuous feedback in an effort to prevent underage access to tobacco. *We Card* has in fact produced new materials specifically for e-cigarette verification.

Proper training and compliance programs are essential elements of any comprehensive plan. The Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or the "Statute") reflects this fact by incentivizing retailers to implement training programs for their employees. Specifically, the Statute stipulates that retailers with "approved" training programs are subject to lower penalties for violations than retailers without such programs.

NACS actively supported the two-tier system for penalties in the Tobacco Control Act. This is because retailers need guidance and incentives to spend the money required to properly train their personnel and institute a compliance program. The Tobacco Control Act was written to encourage retailers to train their employees to comply with FDA's regulations and refrain from selling cigarettes to minors.

Up to this point, FDA has refrained from approving retailer training programs. It has instead issued "guidelines" for training programs without actually "approving" any. As further discussed below, this is not the most effective approach, and further is contrary to the Tobacco Control Act's express directive. Instead, FDA should stipulate that certain programs, such as *We Card*, are "approved" programs that if implemented warrant the Tobacco Control Act's lower penalty schedule.

Approving *We Card* and other training programs as warranting the lower penalty schedule would provide the certainty retailers are looking for in deciding whether to invest resources and staff time in a training program. Importantly, this certainty does not require the regulated community to sacrifice the flexibility afforded by FDA's current policy; indeed, no program need be the exclusive training program approved by FDA. Other training programs that meet the elements outlined in FDA's guidance on the subject[3] could also qualify a retailer for the lower penalty schedule.

The letter of the law is subject to two distinct interpretations, though only one of these interpretations is consistent with the statutory intent described above. The Statute defines an "approved training program" as one that "complies with the standards developed by the Food and Drug Administration for such program."[4] FDA's current interpretation assumes the drafters intended for FDA to develop general guidelines for adequate training programs, and then determine whether individual stores' training programs are sufficient only after violations are discovered but without approving any training programs. This interpretation is flawed. Specifically, it presumes imprecise legislative drafting, and changes the word "approved" to "adequate", "sufficient" or perhaps "compliant", but none of those terms were used. The Tobacco Control Act told the FDA to "approve" training programs that met its standards. Not approving training programs also reduces the incentive for retailers to institute training

[3] "Guidance for Industry: Tobacco Retailer Training Programs," June 2014, *available at* http://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/ucm218898.htm.
[4] Tobacco Control Act, Title 1, Sec 103(q)(2)(B).

programs—which is contrary to the legislation's goal—because retailers will never be certain whether or not their program warrants a lower penalty schedule unless a violation is first identified.

The other interpretation of the statute—whereby FDA approves certain training programs as justifying the lower penalty schedule prior to any alleged violations—better comports with the language and intent of the Tobacco Control Act. The term approved (unlike "sufficient" "adequate" or "compliant") connotes a training program that FDA has itself determined to be compatible with its training guidelines. By making known to the regulated community which training programs FDA believes meet its guidelines, everyone benefits: FDA will better meet its goal of reducing non-compliance with the law because more retailers will adopt training programs that are truly effective; and retailers will be able to make the necessary investments in training time with certainty regarding how they will be treated by FDA in the event a violation does occur. By prospectively approving training programs, FDA would be in a better position to fulfill the Statute's objectives.

B. Warning Statements

1) *Tobacco Product Advertisements*

Under the Proposal, retailers are prohibited from posting advertisements for any tobacco product that do not contain the requisite warning statements as specified in the Proposed Rule. However, the Proposal is unclear as to what constitutes an "advertisement" for tobacco products. For example, presumably a sign that simply notes the availability of tobacco products, without reference to a specific brand name, would not constitute an advertisement. Retailers must be able to inform their customers what products are available in a store without being subjected to a complex regulatory regime. The final rule should clearly spell out what constitutes a tobacco advertisement. And the rule should contain language stipulating that merely stating the availability of tobacco products in a store does not by itself constitute an advertisement.

2) *Individual Cigar Sales*

Under the Proposal, retailers that sell individual cigars must place one of five statements warning customers about the adverse health effects of cigar smoking on an 8.5 x 11 sign on or within 3 inches of *each cash register* where one could purchase an individual cigar. The warning statements must be randomly displayed in each 12-month period in accordance with a rotation plan submitted to and approved by FDA.

NACS has two concerns with the Proposal in this regard: First, the counter-space in a convenience store is extremely valuable. In fact, it is the most valuable display space in a store. It is inappropriate for FDA to require that retailers selling individual cigars forfeit this valuable space. This space is reserved for some of the most profitable items that convenience stores sell. If retailers were required to place a warning sign in this area, retailers would have to move some of their most high margin items to less desirable space in the store, and it would result in a substantial diminution in sales of such products. In fact, the U.S. Circuit Court of Appeals for

the District of Columbia struck down a similar, judicially-imposed warning requirement because it was a taking of this valuable retail space.[5]

Second, the proposal is unclear as to which party would be required to develop and submit rotation plans for warnings signs. With respect to cigarettes, the Tobacco Control Act clearly places this obligation on tobacco product *manufacturers*,[6] and does not authorize FDA to shift this burden to retailers. The final rule should make clear that this obligation falls on cigar manufacturers and not retailers that sell cigars.

C. Comprehensive Enforcement: Online Sales and Tribal Sales

As noted above, NACS's underlying policy objective is to enable its members to sell legal products responsibly and to be able to do so on a level playing field. At the present time, NACS members sell tobacco products on an exceedingly *unlevel* playing field. This is due primarily to sales of tobacco products over the Internet, as well as sales by Tribal governments. The deeming regulation presents an opportunity for FDA to improve this state of affairs. Doing so would not only add equity to the tobacco marketplace but also further the Agency's mission of limiting youth access to tobacco products.

1) *Online Sales*

Online sales of tobacco products need to be regulated by FDA to the same extent that in-store sales have been. The law requires enforcement in both settings and we urge FDA to increase its enforcement regarding online sales and apply the same rules for online e-cigarette sales as it proposes to apply to face-to-face e-cigarette sales.

The Proposed Rule would not regulate Internet sales of newly deemed tobacco products, such as e-cigarettes. This is flawed. By subjecting such products to minimum age restrictions only in brick-and-mortar stores, the Proposed Rule is likely to lead to increased sales of such products over the Internet, where age verification measures are less stringent than in a face-to-face setting.[7] NACS urges FDA to extend the final rule to cover online sales of newly deemed tobacco products.

Section 906(d)(4) (21 U.S.C. 387f(d)) of the Tobacco Control Act directs the FDA to promulgate regulations regarding the sale and distribution of tobacco products that occur through means other than a direct, face-to-face exchange between a retailer and a consumer in order to prevent the sale and distribution of tobacco products to individuals who have not attained minimum age. This reflects Congressional recognition that any effort to keep tobacco out of the

---

[5] *U.S. v. Phillip Morris*, 566 F.3d 1095 (D.C. Cir. 2009).

[6] *See* 15 U.S.C. 1333(a)(4) (warning for tobacco products); *see also* 15 USC 1333(c)(4) (warning for tobacco product advertisements).

[7] *See* Ayers, J.W., K.M. Ribisl, and J.S. Brownstein, "Tracking the Rise in Popularity of Electronic Nicotine Delivery Systems (Electronic Cigarettes) using Search Query Surveillance," American Journal of Preventive Medicine, 40(4): 448-453 (2011) (finding that e-cigarette popularity online has already surpassed that of snus and nicotine replacement therapies which have been on the market far longer than e-cigarettes).

hands of minors must address Internet sales. Up to this point, FDA has not issued such regulations (indeed, it has not even proposed a rule).[8]

This has created a significant loophole in FDA's regulatory regime. When the Proposal is finalized and e-cigarettes are considered tobacco products, that loophole will be enlarged. Youths looking to purchase those products will inevitably gravitate toward online retailers. Congress anticipated such behavior, and obligated the FDA to thwart it by expanding the rules applicable to brick-and-mortar stores to cover the online space as well. Until the FDA complies with its statutory directives, its efforts to keep e-cigarettes out of the hands of minors will be inadequate.

Minors have easy access to tobacco products via the Internet because most vendors do not have adequate age verification methods.[9] "The most common age verification method is self-report, whereby online buyers click a box stating that they are of legal age to purchase tobacco products…or type in a birth date."[10] These methods are obviously not likely to deter adolescents who might lie about their age.[11] Though we are not aware of recent surveys exploring how many teenagers and other youth are buying cigarettes and other tobacco products over the Internet, a 2006 study of 101 Internet websites selling in California found that none of them complied with the state's laws regarding age and ID verification to stop sales to kids.[12] Additionally, attorneys general from at least 15 states have conducted Internet "stings" and found that children as young as nine years old were easily able to purchase cigarettes. A sting operation in New York found that 24 of 26 web sites sold to minors.[13]

The FDA's current efforts to regulate online sales of tobacco should be improved, and further should encompass sales of newly deemed tobacco products.

2) *Sales by Native American Tribes and Tribal Retailers*

The Tobacco Control Act explicitly states that its requirements apply equally to Tribal sellers as well as non-Tribal sellers.[14] Up to this point, the FDA does not appear to be fulfilling this statutory requirement. A very small minority of Warning Letters on FDA's website are targeted to tribal sellers. Tribal retailers sell all of the products that the Proposed Rule would bring under FDA's jurisdiction. Moving forward, FDA's enforcement operations with regard to

---

[8] *But see* Advanced Notice of Proposed Rulemaking, "Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products," 76 Red. Reg. 55835 (September 9, 2011).

[9] See Ribisl KM, Kim AE, William RS. "Web sites selling cigarettes: how many are there in the USA and what are their sales practices?" Tobacco Control. 2001l 10:352-359.

[10] Ribisl, Kurt M., Williams, Rebecca S, and Kim. Annice E., "Internet Sales of Cigarettes to Minors," Journal of the American Medical Association (JAMA) 290(10): 1356-59, September 10, 2003.

[11] See generally Ribisl, Kuth M., Kim, Annice E., and Williams, Rebecca S., "Are the Sales Practices of Internet Cigarette Vendors Good Enough to Prevent Sales to Minors?" American Journal of Public Health, June 2002, Vol. 92, No. 6 ("Youth who misrepresent their age and obtain a money order could potentially purchase cigarettes on-line without difficulty.").

[12] Williams, RS et al., "Internet cigarette vendors' lack of compliance with a California state law designed to prevent tobacco sales to mnors," Archives of Pediatrics and Adolescent Medicine, 160:988-989, 2006.

[13] Unger, JB et al, "Are adolescents attempting to buy cigarettes on the Internet?," Tobacco Control 10: 360-63 (Winter), December, 2001.

[14] 21 USC 387a-1(a)(5).

tribal retailers – both brick-and-mortar and online – should be equally as stringent as those with regard to non-tribal retailers. And tribes simply cannot provide that enforcement. Many tribes are tobacco retailers themselves. They cannot be expected to enforce the law against themselves any better than private companies self-police. The FDA needs to ensure there is real federal enforcement of its rules against tribal sellers.

FDA should also work with other federal agencies to combat illicit tax-free sales (both online and face-to-face) of tobacco products by tribal retailers. Native American tribes are exempt under federal law from charging state excise taxes on sales of tobacco to *members of their own tribes.* Unfortunately, many tribes and tribal retailers are abusing this special tax exemption by expanding it to sales of tobacco to *non-Native Americans.* It is widely accepted that one of the best ways of discouraging youths from consuming tobacco products is by raising the price of such products. It therefore falls squarely within FDA's mission to minimize tribal tax avoidance.

D. "Accessory" vs. "Component"

Under the Proposed Rule, "components" of tobacco products (such as papers, filters, flavoring, etc.) would be subject to FDA authority (requiring minimum age of purchase, a warning statement, etc.), while "accessories" of tobacco products would not be subject to such authority. Although the preamble to the Proposal provides some further detail on the distinction between the two types of products,[15] such distinctions should be memorialized in the text of the final rule. Without clear regulatory text, retailers will not know their regulatory obligations with respect to a category of products that they sell. As the Proposal is currently written, individuals inspecting retail outlets on behalf of FDA will have too much discretion to punish retailers who are in good faith trying to comply with the law.

E. Effective Date

Under the Proposal, the effective date for the deeming provisions and the minimum age and identification restrictions is just thirty days after the date the final rule is published in the Federal Register. This is not enough time for retailers to adjust employee training material, raise awareness of the new requirements, and train and educate employees to ensure proper compliance.

NACS urges FDA to revise this effective date in the final rule to <u>120 days</u> after the rule is published in the Federal Register.

[15] *See* 79 Fed. Reg. 23153 (April 25, 2014).

IV. Conclusion

I hope these comments are helpful, and as always am happy to discuss any of the topics addressed above at any time.

Sincerely,

Lyle Beckwith
Sr. Vice President
Government Relations
NACS