



June 7, 2010

**VIA FAX (301.827.6870)**

Lawrence R. Deyton, MSPH, M.D.  
Director  
Center for Tobacco Products  
U.S. Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850-3229

Dear Dr. Deyton:

On behalf of the National Association of Convenience Stores ("NACS"), I am writing to express NACS members' need for, and sincere determination to ensure, an orderly and effective implementation of the Food and Drug Administration's ("FDA's") "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (the "Final Rule") pursuant to the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"). With the June 22 effective date of the Final Rule fast approaching, NACS requests an opportunity to clarify and hopefully resolve many outstanding issues and questions that each retailer will face in the coming weeks.

NACS is an international trade association representing more than 2,200 retail company members. Our member companies do business in nearly 50 countries worldwide, with the majority of members based in the United States. The U.S. convenience store industry, with some 145,000 stores across the United States, posts approximately \$624 billion in total sales on an annual basis. The majority of our members are small, independent operators. Indeed, more than 70 percent of our total membership is companies that operate 10 stores or less. Over 60 percent are owned and operated by someone who only has one store.

The number one in-store item for the industry is by far tobacco products. This is also one of the most regulated products that the industry sells. As a result, NACS has played a prominent role in the development of United States tobacco policy for the last two decades; its membership has a deeply vested interest in the outcome of both the policy and enforcement choices that FDA makes.

From time to time, NACS may disagree with the policy choices that FDA makes, or its decisions on enforcement matters, but it strongly desires to inform its members of the rules and regulations that may be applicable to them. Given our members' critical role in the tobacco marketplace, we hope that the FDA will recognize that it will considerably enhance its efforts to implement the Tobacco Control Act effectively if it provides NACS with the information it needs to educate its members.

To this end, NACS has devoted considerable resources and member attention to the implementation of the Tobacco Control Act. For instance, just days after the announcement of the Final Rule, NACS conducted a "webinar" for its members to provide information on the rule and answer members' questions. We have also participated in FDA's various rulemakings and requests for comment, and will continue to do so. In short, NACS has done everything in its power to ensure that its members remain good business citizens when it comes to tobacco matters.

We therefore appreciate FDA's June 3, 2010, "Draft Guidance for Industry: Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents" (the "Draft Guidance"). While the Draft Guidance is helpful in confirming many of the central compliance aspects of the Tobacco Control Act and the Final Rule, however, it does not provide authoritative assistance to NACS members on a range of issues.

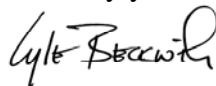
NACS therefore requests that, at the earliest possible time, it be afforded an opportunity to meet with FDA Tobacco Center officials to address all of the regulatory uncertainties associated with the implementation of the Final Rule. Some of our questions are remarkably simple (*e.g.*, may a retailer give away a free pack of matches with the purchase of a pack of cigarettes?), while others may raise issues that will assist NACS to work together with the FDA in the future (*e.g.*, the choice of retailer training programs).

Please find attached a Question and Answer document developed by NACS and its counsel that is based on the questions that our members have raised. In the answers to these questions, NACS has chosen a very conservative approach, seeking to err on the side of the possible need for regulatory compliance, rather than advocating for lesser or no compliance burdens. Thus, for instance, the document answers the question above relating to matches using the plain language in the Final Rule, even though NACS believes the result borders on the absurd. It is precisely in areas such as this one that NACS needs FDA's detailed guidance.

We propose a face-to-face meeting with Tobacco Center officials of your choosing as soon as possible to discuss these matters.

Thank you in advance for your favorable consideration of this request. Please do not hesitate to contact me or Mr. James Barnette (202.429.6207), who serves as counsel to NACS, if I may help to facilitate the meeting that we propose.

Sincerely yours,



Lyle Beckwith  
Senior Vice President, Government Relations

Attachment



## **FDA REGULATION OF RETAIL TOBACCO SALES**

### **QUESTIONS FROM MARCH 22, 2010 WEBINAR**

In June 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Act”), which comprehensively addressed the manufacture, distribution, and retail sales of tobacco products, as well as related issues. On March 19, 2010, the Food and Drug Administration (“FDA”) published a final rule in the Federal Register (the “Rule”) that implements the new law in significant part.

NACS hosted a webinar to provide its members with information about the new Rule and received dozens of questions. Below, NACS counsel addresses these questions, and points out where there may be ambiguities in the Tobacco Act and/or the Rule that FDA will need to resolve over time.

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## **Effective Date**

*When will the Tobacco Act become effective?*

The Act itself became effective on the date it was signed – June 22, 2009 – but its individual provisions have many different effective dates. Some provisions, such as the ban on the sale of flavored cigarettes (see below), became law soon after the bill was signed and are currently being enforced.

*When will the new Rule become effective?*

The regulations governing the retail sale of tobacco published on March 19 will become effective on June 22, 2010. Most of what follows relates to the various requirements of the Rule.

## **Scope of the Rule**

*What products are subject to regulation under the Rule?*

The Rule governs virtually every aspect of the retail sale of “cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.” “Smokeless tobacco” includes “snuff.”

*Are cigars, little cigars, pipe tobacco or other products subject to the Rule?*

No. Retailers should be aware that there are state laws which may govern the sale of these products, however. Also, the Tobacco Act does give the FDA authority to regulate cigars and other products in the future.

*Do the regulations apply to sales on Indian reservations?*

Yes.

*Do the regulations apply to sales over the Internet?*

The Rule exempts Internet sales from its requirements for age verification, but the Act requires that FDA promulgate rules that both apply age verification to Internet and mail order sales and apply advertising restrictions to those sellers. In addition, Congress passed the Prevent All Cigarette Trafficking Act (PACT Act) on March 17, 2010. That law requires that Internet sellers collect and remit taxes on their sales just like brick and mortar retailers and requires that they verify age. The Department of Justice has the authority to enforce the PACT Act against Internet sellers. The PACT Act takes effect 90 days after it becomes law and it is currently awaiting the President’s signature.

*Is flavored rolling paper included in the ban on flavored cigarettes?*

Yes. See below.

*What about electronic cigarettes?*

The Rule does not address electronic cigarettes. The regulatory status of electronic cigarettes is currently the subject of a dispute in the courts. The FDA's assertion that it can regulate electronic cigarettes has been challenged. That litigation must be resolved for there to be any clarity regarding the sale of electronic cigarettes.

*What about clove cigarettes?*

Clove cigarettes are considered "flavored" (see below), and their sales are completely prohibited under the Act.

### **Underage Sales**

*Do the clerks working the store register really have to "card" anyone who is under 27?*

The short answer is yes. The age verification requirement has generated a great deal of confusion, primarily because the Rule is written with a great deal of ambiguity.

The Rule says that (1) cigarettes and smokeless tobacco may not be sold to those under 18; (2) each retailer must "verify that no person purchasing the product is younger than 18;" and, (3) "no verification is required for any person over the age of 26." Of course, there is no magic way to determine whether someone is over 26 without checking an ID. As a result, retailers are well-advised always to err on the safe side, instructing clerks to verify the age of any purchaser who might be under 27 years of age.

*Is it a violation of the Rule if I fail to check ID on someone that turns out to be, say, age 24?*

It appears so. Although the Rule does not address this issue directly, it does say that verification is not required for people over 26. That at least implies that there is a requirement to verify age for anyone younger than 27, and that the failure to do so amounts to a violation, subject to enforcement penalties. Again, retailers are advised to err on the safe side. FDA may clarify this question in future regulations.

*Can I accept an out-of-state driver's license as proof of identification?*

Yes.

*Can children buy cigarettes for their parents or other adults?*

No. All purchasers must be at least eighteen years of age.

*Can an adult (18 or over) purchase a pack of cigarettes and then hand it to someone who is clearly not 18?*

Yes. The regulations only apply to the purchase, but retailers would be well advised to ensure that they do not make sales to adults when they know that the cigarettes are being purchased for someone under 18.

*If underage people can't buy cigarettes, can I give away free cigarette samples?*

No.

*Does the age requirement apply to the purchase of rolling papers?*

No. The Rules apply only to purchases of cigarettes and smokeless tobacco products.

*Do my clerks have to be 18 in order to sell cigarettes?*

The Rules do not address the age of the salesclerk. Retailers should be mindful, however, of state laws that do.

## **Face-to-Face Transactions**

*Do I have to have a clerk process every cigarette or smokeless tobacco transaction?*

Yes, without exception.

*Can I continue to use a vending machine if I make sure a clerk keeps an eye on who is using it?*

No. The Rule makes very clear that (with the exception of adult-only facilities), neither cigarettes nor smokeless products may be sold from a vending machine.

*I have a large display on my store floor that includes cigarette cartons and single packs. Customers pick up their brand, and bring it to the counter where I can verify age. Is the display OK?*

No. All “self-service displays” are prohibited as of June 22. Customers may not have any independent access to cigarettes or smokeless tobacco; they must ask for and receive it from a store clerk. The products must be kept out of reach from customers



until the time of sale either by putting the product behind the counter or, if on the floor, in a locked display.

*Is a drive-thru sale permissible?*

Yes, so long as the customer does not have access to the product before the point of sale and the age verification requirements are followed.

*If the customer gets a carton of cigarettes from a clerk, can the customer then complete the purchase in a self-checkout lane? Or do they have to actually pay in a face-to-face transaction?*

The customer must pay in a face-to-face transaction. Self-checkout sales of cigarettes and smokeless products are prohibited.

*What about tubes, papers, rolling machines? Behind the counter?*

The Rule does not require that tubes, papers, or rolling machines be removed from customer contact.

### **Coupons, Gifts, and Giveaways**

*Can I still accept manufacturer coupons for cigarettes and smokeless tobacco?*

Yes.

*Can I accept any kind of coupon that gives a customer something for free when he buys a carton of cigarettes?*

No. So, for instance, a retailer may not accept a coupon that appears to entitle a customer to a free hat or some other product connected to the purchase of cigarettes or smokeless tobacco.

*Can I give out free samples of cigarettes?*

No. No retailer, even in an adult-only facility, may provide free samples of cigarettes.

*Can I give out free samples of smokeless tobacco?*

Yes, but ONLY in qualified, temporary adult-only facilities (see below). The Rule places limits on the number and amount of such free samples.

*Does the FDA Rule affect coupon offers where retailers must provide customers with a \$2 off coupon if the retailer is out of stock on one of the targeted items?*

No. As long as the coupon is not conditioned on someone purchasing tobacco, the Rules do not limit its use

*I give away a free lighter with the purchase of every carton of cigarettes. Will that still be OK? Can I give out free matches?*

No. The FDA is likely to consider either lighters or matches as a “gift” accompanying the purchase of the cigarettes, which is prohibited under the Rule.

*Can I package a carton of cigarettes with a deck of cards or another item as a promotion?*

No. The cards would be deemed a gift, which is prohibited.

*Can I do a “Cigar Night” promotion, packaging four cigars and a couple decks of cards?*

The Rule does not prohibit that promotion because it does not regulate cigar sales. State laws may provide otherwise.

*I sometimes have promotions when customers can buy a certain amount of smokeless (say, 10 tins) and get two free? Can I continue those?*

Yes.

*I have a loyalty program in which customers get rewards for in-store purchases. Can purchases of cigarettes and smokeless tobacco count toward this program?*

No, the Rule prohibits people from getting any type of free gift or item for purchasing cigarettes or smokeless tobacco. A retailer could, however, have a tobacco only rewards program in which the purchase of cigarettes or smokeless tobacco earned rewards on future purchases of cigarettes or smokeless tobacco.

*Can a retailer SELL tobacco product branded products like t-shirts, hats, mugs, etc completely separate from any other purchases?*

As of June 22, manufacturers and distributors are prohibited from selling non-tobacco items, like T-shirts and novelty items, bearing a cigarette or smokeless tobacco brand-name, logo, or selling message. So while there is no express prohibition on retail sales of these items, retailers are well-advised to stop selling them as of that date.

## **Enforcement**

*If there is a violation, who is fined? The owner of the store or the employee who committed the violation?*

Under the Tobacco Act, the “retailer” is held liable. While a retailer under the Act could be an individual person, we interpret the Act to mean that, fines for making an underage sale would be assessed against the company that owns the store in which the violation took place.

*In calculating the number of violations for underage sales and the escalating penalties associated with repeat violations, will violations be counted on an individual store basis or chain wide? That is, if a chain has one violation within a year at 20 different stores, will the penalty for the violation at the 20th store be treated the same as the violation at the first store?*

The Tobacco Act states that the imposition of a no tobacco sale order applies to a specific location – not chain wide. The language for the application of monetary penalties is less clear, but appears to apply on a per location basis as well. FDA must write guidance dealing with these questions and we expect it to verify that the violations are counted per location.

*If FDA issues a no sale order, does it apply to all the stores that a company owns or a group of franchisees?*

The Act says it applies to a particular location but FDA must write guidance to verify this.

*When can FDA impose a no tobacco sale order?*

FDA must adopt guidance defining “repeated violation” for purposes of imposing a no sale order. According to the Act, FDA must allow for at least 5 violations within a 36 month period at a particular retail outlet before imposing such an order.

*Apparently the amount of the civil penalty imposed for repeated violations depends on whether the retailer has an “approved” training program. Any idea what such a program might look like?*

The FDA is conducting a proceeding now to determine how to approve training programs and what those programs should require. NACS submitted formal comments to FDA in this proceeding, arguing strongly that the We Card program should be designated as an approved program.

*What impact will the Tobacco Act have on enforcement and who will do the compliance checks? I have heard that retailers should expect more visits at their locations checking for underage sales.*

The FDA is required to work with the states on inspections and is seeking to contract with state and local governments to carry out these duties. FDA also has its own authority to conduct them. The Act does provide that a federal fine should be adjusted downward based on the amount of any state fine imposed for the same violation. It should not come as a surprise to retailers if the number of inspections increases after June 22.

*Is the number of violations cumulative over time?*

Not entirely. For underage sales, violations accumulate over specific periods (from one to four years, on a rolling basis) for the purpose of determining the appropriate penalty. In general, a violation will no longer count toward escalating fines after 4 years. It is possible, however, that FDA could consider such violations in the context of a decision to impose (or later rescind or modify) a no tobacco sale order. FDA will write guidance regarding what might subject retailers to a no tobacco sale order.

*Can you provide a copy of the penalty schedule?*

A copy of the penalty schedule for underage sale violations is attached.

### **Advertising**

*Is tobacco advertising limited to black and white text?*

The Rule limits all advertising of cigarettes and smokeless tobacco to black text on a white background. Right now, however, a U.S. District Court in Kentucky has issued an order stating that this part of the rule violates the First Amendment and cannot be enforced. It is not clear whether that ruling might change after all potential appeals are completed. For now, this restriction will not be applied by FDA, but that could change in the future based on the course of the litigation.

FDA has broad powers under the Act to restrict advertising of tobacco products if it finds that to be appropriate for the protection of public health and NACS will continue to monitor future actions by FDA in this area.

*Is there a prohibition on outdoor advertising within 1,000 feet of a school or playground and how is that measured?*

The FDA did not include this prohibition in the Rule. While the rule published in 1996 did prohibit outdoor advertising within 1,000 feet of a school or playground, a similar rule in Massachusetts was overturned by the U.S. Supreme Court several years ago. In light of that decision, FDA has not published any rules on outdoor advertisements and instead is soliciting comments about what outdoor advertising restrictions should be applied and would be consistent with the First Amendment.

Until the FDA receives comments and releases a proposal there is no way to know what restrictions on outdoor advertising there might be and whether those restrictions would apply to signage within a store that can be seen from outside.

*Are we required to say the name of the product (such as “cigarette”) in ads for tobacco products?*

No. While this requirement was part of the 1996 rule published by FDA, the legislation instructed FDA to remove it in the newly published rules.

*Can we advertise cigarettes along with smokeless tobacco?*

Although a literal reading of the Tobacco Act prohibits marketing cigarettes and smokeless tobacco together, we do not consider that to be the intent of Congress. The FDA may issue future guidance to clarify this point.

### **Flavored Cigarettes**

*When does the prohibition on the sale of flavored cigarettes go into effect?*

The prohibition went into effect in September 2009. FDA has already enforced the prohibition against some retailers.

*How does the FDA define a flavored cigarette?*

The Tobacco Act provides the definition: “a cigarette . . . (including the tobacco, filter, or paper) [that] contain[s an] . . . additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.” That means neither rolling paper nor tobacco (in addition to complete cigarettes) can be flavored. Because this definition is so broad, retailers should avoid the sale of all flavored cigarettes.

## **Adult-Only Facilities**

*Are vending machines and self-service displays permissible?*

The Rule permits such sales only in facilities where persons under the age of 18 are prohibited from entering.

*Can I provide free samples of smokeless tobacco?*

Yes, but ONLY in qualified, temporary “adult-only facilities.” Such facilities are defined at great length in the Rule. The facility must:

- require each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity, government-issued identification showing a photograph and a birthdate;
- may not sell, serve, or distribute alcohol;
- may not be located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;
- be a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco;
- be enclosed by a barrier that--
  - is constructed of, or covered with, an opaque material (except for entrances and exits)
  - extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and
  - prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and
  - does not display on its exterior—
    - any tobacco product advertising;
    - a brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or
    - any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship.

Obviously, these requirements are intended to be stringent.



*Can I provide free samples of cigarettes in an adult-only facility?*

No.

*Can a retailer create an adult-only section of the store?*

It would not be possible to have an adult-only section for purposes of providing free samples of smokeless tobacco. It might be possible to create an adult-only section for purposes of having a vending machine or self-service display. The Rule is not clear on this point, but retailers should be aware that if they create such a section and are not vigilant about keeping it adult-only, the presence of minors in that section (or failure to verify age prior to admittance to that section) could be considered a violation of the Rule and trigger potential fines and no sale orders.