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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Tobacco Retailer Training Programs Draft Guidance
Comments from the Campaign for Tobacco-Free Kids
Docket No. FDA-2010-D-0350

To Whom It May Concern

As discussed below, there are a number of ways that FDA could improve the Tobacco Retailer Training Program Draft Guidance before issuing it in final form so that it would work even more effectively to encourage the development and implementation of effective retailer training programs that will work directly to prevent and reduce tobacco product sales to youth. But the most troubling element of the Draft Guidance is the statement that, until final regulations to establish formal standards for approved retailer training programs are in place, FDA intends to apply the lower maximum civil money penalties schedule in the Family Smoking Prevention and Tobacco Control Act (FSPTCA) – which the law applies only to retailers with FDA-approved training programs – to all retailers who violate the regulations prohibiting the sale of cigarettes or smokeless tobacco to youth, even if they do not have any training program of any kind.

That stated intention of FDA directly contradicts the FSPTCA, which explicitly states that the lower maximum penalties may apply only to retailers with an approved training program. [Section 103(q)(2)(A)] FDA clearly does not have the legal authority, under the FSPTCA, to reduce the maximum penalty amounts for any retailer that does not have an FDA approved training program.

For retailers without an approved training program that violate the regulations prohibiting sales and distributions of cigarettes and smokeless tobacco to youth, FDA is, of course, free to determine what penalty amounts it will apply *within the applicable maximum penalties for retailers without approved training programs*. But FDA does not have the authority to reduce the maximum applicable penalties across-the-board, before the violations occur, for all future retailers who violate the regulations, regardless of the individual circumstances of those violations.

Besides not being permitted by the FSPTCA, such an across-the-board, anticipatory reduction of applicable maximum penalties would open the door to retailer abuses. Among other things, it would give all retailers a completely free pass for their first violation – regardless of how intentional or gross the violation was, and even if the retailer had made no attempt at all to train its staff to comply with the regulation or had even trained them how to evade compliance –

subjecting the violating retailer, at most, to a warning letter. At the same time, the economic risk to retailers for second and third violations would be cut in half. Because FDA is still developing its monitoring and enforcement mechanisms for retailer compliance, the chances that a retailer which violates the regulation will be caught is still relatively low. Coupling that lower risk of being caught with sharply reduced maximum penalties is inviting retailer carelessness if not intentional misconduct.

Until final regulations are issued to establish formal standards for approved retailer programs to qualify for the lower statutory penalties, FDA must inform retailers that, by law, the penalty amount maximums for retailers without approved training programs must apply to all retailer violations of the regulations prohibiting sales or distributions to youth. To be fair, however, FDA could also notify retailers that FDA will consider whether or not a violating retailer has made a good faith effort to train its staff to comply with the regulations in determining the final penalty amount that will actually be applied. FDA might also state that only those violating retailers that have absolutely no training program at all will be subject to possibly having to pay the very highest penalties allowed under the applicable maximums. But no retailers should be told that they will automatically be subjected, at worst, to only a warning letter for a first violation, and no retailers should be freed from any risk of the higher penalties for those without approved training program, without at least some fact finding as to the seriousness of their violation and the quality of their staff training efforts.

Other Concerns and Suggestions

The Draft Guidance does a good job describing what retailers must and must not do under the FSPTCA and the related final rule implemented on June 22, 2010, which apply to the sale and distribution of cigarettes, roll-your-own tobacco and smokeless tobacco. But it should also clarify the reach of the applicable definitions of cigarette and roll-your-own tobacco. While the Draft Guidance includes the text of the applicable definitions under its "What definitions apply?" section, it does not say anything about how FDA will interpret and apply those definitions. At the very least, the Guidance should say that FDA will apply the laws and regulations pertaining to retailers to the sale of any cigarettes or roll-your-own tobacco for cigarettes that fit the stated definitions, even if the cigarettes are labeled as "little cigars" or "filtered cigars" or if the RYO tobacco for cigarettes is labeled as "RYO tobacco for cigars" or as "pipe tobacco." FDA could also provide further guidance and, ultimately, issue a new rule to clarify what tobacco products are still cigarettes or RYO cigarette tobacco under the FSPTCA and related regulations, despite being labeled as something else. But to put manufacturers and retailers on notice that this kind of false labeling will not be ignored or accepted by FDA, this important issue should at least be mentioned in this and other FDA guidance documents, even before any further guidance or new rule can be issued to clarify the precise scope of the definitions.[1]

The Draft Guidance regarding the desirable characteristics of any retailer training program is, for the most part, excellent. To try to make it even better, the Campaign for Tobacco-Free Kids offers the following suggestions.

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[1] For more on the problem of RYO tobacco falsely qualifying as "pipe tobacco" to evade proper taxation and regulation, see the comments submitted to FDA by Matthew Myers, Campaign for Tobacco-Free Kids, Docket No. FDA-2009-N-0294-1035, posted December 31, 2009, http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a6fc38.

- At page 8, the three elements of an effective retailer training program should be expanded to include "(4) successfully follow all other restrictions and requirements pertaining to the sale and distribution of tobacco products at retail outlets; and (5) know how to safely and confidentially report sales to youth or other violations to the management of the business and to FDA."

- At page 8, under "Applicable Laws and Penalties," the text should also encourage retailers to inform their staff that federal law:
  - forbids the distribution of free samples of any tobacco products (not just cigarettes, RYO cigarette tobacco and smokeless tobacco) at any retail outlets;[2]
  - forbids the sale or distribution at retail of loose cigarettes or cigarettes in packages of fewer than 20 cigarettes;
  - forbids the sale or distribution at retail of any cigarette tobacco or smokeless tobacco outside of the packages provided by the manufacturers;
  - forbids giving purchasers of cigarettes, cigarette tobacco or smokeless tobacco at retail any gift or other item linked to the purchase or to a prior purchase of cigarettes, cigarette tobacco or smokeless tobacco.

- At page 9, under "Health Effects of Tobacco Use," text should say that the economic burden of tobacco use is estimated to total *well in excess* of $193 billion annually. The cited CDC data from which the $193 billion estimate comes from pertains only to smoking costs and productivity losses, is in 2004 dollars, and includes only those productivity losses from premature smoking-caused death cutting useful worklives short (not including productive worklives being cut even shorter by smoking-caused disease or disability prior to death, and not including productivity losses from smokers taking more sick days than nonsmokers and being less productive when on the job).

- At page 9, the section on "Written Company Policy Against Sales to Minors" should be expanded to encourage retailers to adopt, enforce and familiarize staff with formal written policies not just against sales to youth but also in conformity with other applicable requirements and restrictions under federal law (e.g., no free samples, no selling cigarettes or smokeless tobacco products outside of manufacturer packages, no gifts linked with sales) and under state or local law.

- At page 9, in regard to the retailer training clearly defining which tobacco products are subject to the federal tobacco control act and related regulations, the guidance text should be expanded to provide additional information about how the training should explain that the law and rules reach cigarettes even if they are labeled as "cigars" and reach cigarette tobacco even if it is labeled as "cigar tobacco" or "pipe tobacco." As noted above, simply re-stating the statutory definitions does not provide adequate guidance.

- At page 11, under "Practical Guidance for Requesting Identification and Refusing Sales to Underage Youth," the Guidance should also encourage training programs to instruct staff on

[2] FDA should also quickly initiate a rule-making procedure to include all other tobacco products in the regulation prohibiting the sale of cigarettes, RYO cigarette tobacco, and smokeless tobacco to youth.

how they can quickly get support from other staff, ideally management personnel, when pressured or otherwise confronted by a customer who will not provide ID or challenges the staff person's refusal to sell the customer tobacco products.

- At page 12, the testing section should also encourage retailers to ensure that the tests are comprehensive (so taking, or re-taking, the test reinforces all the key information staff should know). In that regard, staff allowed to sell tobacco products after getting 75% (or, even better, 80%) correct on the test should also be required to continue re-taking the instructional written test on a weekly or at least monthly basis until they get 95% correct or higher. The Guidance should also provide more information on what the test should cover and also provide guidance as to its form (e.g., not just a list of obvious true or false questions).[3]

- At page 14, the third paragraph under subsection D ("How will civil money penalties be assessed for violations of regulation?") should also notify retailers that, if they receive a notice of Complaint and seek to have their penalties reduced because they have a training program in place, they will have to show that show that all staff involved in the violations, including the managers of the sales staff, had previously received the initial training, as well as any required refresher sessions, and had passed all related tests – and will also have to show that remedial action, pursuant to the training program, was taken after the violation occurred.

With these changes, the final Tobacco Retailer Training Programs Guidance should effectively encourage tobacco product retailers to implement staff training programs that will actually make a difference in reducing tobacco product sales to youth and preventing other violations of the FSPTCA and related regulations. More importantly, they will set a strong foundation for the new regulations FDA plans to implement to establish formal standards for approved retailer training programs. As detailed in the Campaign for Tobacco-Free Kids previously submitted comments on this topic, relying on industry-sponsored or purely voluntary programs to prevent sales of tobacco products to youth and related retailer violations simply do not work.[4] But

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[3] While this kind of comprehensive and repeated staff testing, along with the other staff training requirements in the Draft Guidance, might seem excessive to some, research has found that the behavior of retailer sales clerks, rather than the behavior of the youth trying to make underage purchases, is actually the strongest predictor of cigarettes sales to youth. [Klondoff, A. & H. Landrine, "Predicting Youth Access to Tobacco: The Role of Youth Versus Store-Clerk Behavior and Issues of Ecological Validity," *Health Psychology* 23(5): 517-524, September 2004.] It is also clear that until retailer compliance rates exceed 90 percent it will remain too easy for youth to purchase cigarettes and other tobacco products and there will be no significant related reductions to overall youth smoking and other tobacco use rates. [See, e.g., DiFranza, JR, **"**Are the Federal and State Governments Complying With the Synar Amendment?," *Archives of Pediatrics & Adolescent Medicine* 153(10):1089-1097, October, 1999("All of the studies that have demonstrated a decreased availability of tobacco to minors, as evidenced by a reduced prevalence of tobacco use, have achieved violation rates below 10%.")].

[4] Comments submitted to FDA by Matthew L. Myers, President, Campaign for Tobacco-Free Kids, Docket No. FDA-2009-N-0569-0011, posted January 8, 2010, http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a7889d.

retailers do reduce their tobacco product sales to youth and otherwise improve their compliance with applicable laws and regulations when faced with clear standards, significant financial incentives, and effective enforcement.[5]

Sincerely,

Matthew L. Myers
President
Campaign for Tobacco-Free Kids

[5] Comments submitted to FDA by Mathew L. Myers, FDA-2009-N-0569-0011, January 8, 2010.