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December 23, 2009

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

Re: Docket No. FDA-2009-N-0294

To Whom It May Concern:

Because the definition of “cigarette” in the Family Smoking Prevention and Tobacco Control Act (FSPTCA) includes roll-your-own (RYO) tobacco, the FSPTCA provisions that apply to cigarettes, such as the new ban on flavored cigarettes, also apply to tobacco used for RYO cigarettes. To make sure all RYO cigarette tobacco will be reached by any FSPTCA provisions pertaining to cigarettes, the law defines RYO tobacco broadly:

“The term ‘roll-your-own tobacco’ means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.”

Nevertheless, it is likely that RYO tobacco manufacturers will try to evade compliance with the FSPTCA by changing the labeling of their RYO cigarette tobacco and claiming it is no longer RYO cigarette tobacco but is either RYO tobacco just for cigars or even pipe tobacco.

In fact, there is clear evidence that manufacturers have already started re-labeling cigarette RYO tobacco as “pipe tobacco” to try to evade the higher federal tax rates on RYO tobacco compared to pipe tobacco. As the Alcohol and Tobacco Tax and Trade Bureau (TTB) noted in a recent proposed rule to address this problem, the much lower federal tax for pipe tobacco compared to RYO tobacco creates a strong financial incentive for tobacco product manufacturers to present RYO tobacco as “pipe tobacco” in the marketplace. In fact, in the first five months after the new tax rates went into effect, TTB data show that federally-taxed RYO tobacco sales dropped by 51%, compared to the same period the year before, while federally-taxed “pipe tobacco” sales increased by 167%, with no evidence of any similar changes in the actual numbers of pipe smokers or RYO users.<sup>1</sup>

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<sup>1</sup> See, e.g., Apuzzo, M, “AP IMPACT: Tobacco execs quickly find tax loophole,” *Associated Press*, November 17, 2009, [http://news.yahoo.com/s/ap/20091117/ap\\_on\\_bi\\_ge/us\\_tobacco\\_tax\\_loophole](http://news.yahoo.com/s/ap/20091117/ap_on_bi_ge/us_tobacco_tax_loophole), with related video available at: <http://www.youtube.com/watch?v=OWOqpQ06Guc>.

It is highly likely that the manufacturers of all the cigarette RYO tobacco that is evading higher federal taxes by being repackaged and re-labeled as “pipe tobacco” will also try to evade compliance with all of the provisions in FSPTCA that apply to cigarettes, including RYO cigarette tobacco, but not to cigars or RYO cigar tobacco. Indeed, some of the new RYO cigarette tobacco re-labeled as “pipe tobacco” is offered for sale in different flavors that are prohibited for cigarettes and cigarette RYO tobacco by the FSPTCA.

To address this problem, the FDA should issue a formal guidance that states that any tobacco marked as RYO tobacco for cigars or as pipe tobacco will still be subject to the FSPTCA as RYO cigarette tobacco if its packaging, including inserts or onserts, or its advertising or marketing includes any words or messages of any kind that indicate that the tobacco can also be used as tobacco for RYO cigarettes. Otherwise, manufacturers of RYO cigarette tobacco could try to escape complying with the FSPTCA by re-labeling the RYO tobacco as “pipe tobacco” while still having text on the packaging stating that the tobacco was “also suitable for roll-your-own cigarettes” or “may also be used to make RYO cigarettes.”

Even with that change, however, some RYO cigarette tobacco might still inaccurately qualify as pipe tobacco or as RYO tobacco only for cigars, and possibly escape compliance with the FSPTCA flavored ban and other provisions, if its packaging and advertising did not make any references at all to RYO cigarettes. While the absence of any reference to RYO cigarettes would help to impede efforts to sell the re-labeled RYO cigarette tobacco to consumers seeking RYO cigarette tobacco, tobacconists and others sellers of tobacco products could simply notify their customers that the “cigar RYO tobacco” or “pipe tobacco” was actually RYO cigarette tobacco, and, thanks to modern communications, that would quickly become widely known among smokers of RYO cigarettes.

FDA should, therefore, also establish and enforce clear criteria for identifying the tobacco that qualifies as cigarette RYO tobacco subject to the FSPTCA no matter how it is labeled. One possibility, for example, might be to say that any tobacco consisting primarily of flue-cured or burley tobacco (used in cigarettes) will be considered RYO cigarette tobacco subject to the FSPTCA, regardless of its labeling or the text on its packaging.<sup>2</sup>

Tobacco manufacturers have clearly demonstrated their ability and willingness to make changes to the packaging and labeling of their products to circumvent the laws and the intent of Congress. Indeed, this problem of RYO cigarette tobacco being relabeled as “pipe tobacco” follows right on the heels of the problem of cigarettes putting tobacco into their wrappers and changing their

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<sup>2</sup> Given TTB’s existing expertise pertaining to the different types of tobacco products and their characteristics – and the fact that TTB is confronting parallel problems – it would likely be constructive for FDA to work with TTB and coordinate its mutual efforts to ensure that no tobacco products are able to evade proper compliance with federal law simply by being repackaged or relabeled or through other cosmetic changes.

packaging and labeling in order to try to qualify as “small cigars” in order to evade various state and federal laws.<sup>3</sup>

Given time and expanded capacity, FDA could effectively address these kinds of product-manipulation problems by asserting jurisdiction over all tobacco products and applying the provisions in the FSPTCA that apply only to cigarettes and smokeless tobacco (such as the upcoming Final Rule) or only to cigarettes (such as the flavored cigarette ban) to all tobacco products. In the meantime, FDA should issue guidance to make it crystal clear to manufacturers that the FSPTCA provisions that apply to cigarettes and RYO cigarette tobacco apply not only to tobacco labeled as RYO cigarette tobacco but also to any RYO cigarette tobacco that is packaged or labeled as some other type of tobacco product.

The FSPTCA was passed into law to prevent and reduce tobacco use and its harms, with a special initial emphasis on reducing cigarette smoking and its harms. Toward that end, the new law applies its provisions relating to cigarettes to RYO cigarette tobacco, as well. By clarifying that any and all RYO tobacco is subject to the FSPTCA, regardless of how it is labeled or described, FDA can put tobacco product manufacturers on notice that they will not be allowed to subvert the intent of the new law simply by making superficial changes to their tobacco products or to the tobacco products’ packaging or labeling.

Sincerely,



Matthew L. Myers  
President  
Campaign for Tobacco-Free Kids

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<sup>3</sup> FDA has already taken some steps to address this problem in relation to compliance with the FSPTCA, such as its September 14, 2009 Letter to Industry on Cigarettes Containing Certain Characterizing Flavors, but here, too, FDA should provide additional formal guidance to make it clear that no cigarette will be able to evade compliance with the FSPTCA simply through changes to its wrapper or to its packaging or labeling. See letter submitted by American Cancer Society Cancer Action Network, American Heart Association, Campaign for Tobacco-Free Kids, American Lung Association, and the American Legacy Foundation on August 27, 2009 to Docket Number FDA-2009-N-0294.