July 11, 2014

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

RE: Docket No. FDA-2014-N-0189, and RIN 0910-AG38

To Whom It May Concern:

On behalf of the over 50 organizational coalition members and partners of the North Carolina Alliance for Health (NCAH), we write to applaud the Food and Drug Administration (FDA) in proposing new regulations for electronic cigarettes, hookah tobacco, cigars, and other tobacco products including pipes, nicotine gels, and dissolvables.

The North Carolina Alliance for Health (NCAH) is an independent, statewide coalition of organizations and individuals advocating for policies that promote wellness and reduce the impact of obesity and tobacco use. NCAH was created in 2002 and now includes over 50 statewide organizational members and partners. NCAH has a strong history of successfully influencing statewide public policy change, including leading the advocacy effort to pass the state’s smoke-free restaurants and bars law which went into effect January 2010. A sampling of active NCAH members includes the American Heart Association, the American Cancer Society, the American Cancer Society Cancer Action Network, American Lung Association, NC Pediatric Society, NC Prevention Partners, NC Alliance of YMCA’s, NC Local Health Directors Association, March of Dimes, American Diabetes Association, the NC Health Access Coalition, NC CHILD, AARP, the Council of Churches and many others. NCAH has a strong history of supporting evidence-based policy change interventions to prevent and reduce tobacco use and eliminate exposure to secondhand smoke. We are pleased to have the opportunity to provide comments on this proposed rule.

Tobacco use remains the leading preventable cause of death in North Carolina, responsible for 12,500 deaths in our state each year. Currently, 180,000 North Carolina children aged 0-17 are projected to die from smoking. Medical care alone for smoking related illnesses cost North Carolina $3.8 billion each year. Most North Carolina tobacco users want to quit; in fact 69% of North Carolina smokers ages 18-34 made a serious but failed attempt to quit smoking in 2012.

NCAH strongly supports the proposed regulations that include: 1) prohibiting sales to children under age 18; 2) requiring retailers to verify age for all over-the-counter sales and provide for federal enforcement and penalties against retailers who sell to minors; 3) restricting vending machines to adult-only facilities, prohibiting free samples; 4) requiring all tobacco products containing nicotine to carry an addiction warning and cigars to carry one of four other warnings as well; 5) requiring disclosure of ingredients and documents related to health, prohibiting the introduction of new or
changed products without prior FDA review; 6) prohibiting manufacturers from claiming a tobacco product is less harmful or will expose a consumer to fewer harmful substances without first providing the FDA with scientific evidence; and 7) authorizing the FDA to set standards governing the content of tobacco products.

However, NCAH has three major concerns about what is missing from the proposed regulations. First, while the FDA’s proposal recognizes that fruit and candy flavors can be especially attractive to youth, the FDA has not proposed extending the current prohibition on characterizing flavors for cigarettes to any other tobacco products. If the proposed rule is not strengthened, e-cigarettes and other tobacco products will continue to be marketed and sold in youth-attractive flavors.

Second, although the FDA has the authority, it has not proposed any advertising and marketing restrictions, including on-line and publications with high youth readership for newly covered tobacco products. FDA’s proposal would allow manufacturers to continue to freely advertise its products in ways that are appealing to youth and normalize an addictive behavior that looks identical to cigarette smoking.

Third, the FDA’s proposal would allow manufacturers to freely market new products so long as they submit an application to the FDA within a twenty-four month provisional period. Manufacturers could continue to market their new products until the FDA issues an order prohibiting the products from being on the market. A similar process was established during the passage of the Tobacco Control Act, however, given the fact that as of the date of this published proposed rule, the FDA had only acted on the applications for 4 products and there are 3,396 outstanding applications pending at the FDA, we encourage FDA to re-evaluate this proposed rule in order to effectively handle the potential thousands of new emerging products, especially electronic nicotine delivery products, in a more effective regulatory method.

A 2013 study in the journal Pediatrics reported youth exposure to television advertising for electronic cigarettes increased by 256 percent from 2011 to 2013, exposing 24 million U.S. kids to these ads. The researchers predicted that “if current trends in e-cigarette television advertising continue, awareness and use of e-cigarettes are likely to increase among youth and young adults.” The study showed that the North Carolina Triad area had the most e-cigarette television ad exposure in the United States, as measured by target ratings points compiled by research firm Nielsen. There were 770 e-cigarette television ads in the Triad during the study's time period. The second highest was in West Virginia.

Just as alarming as the proliferation of advertising is the pace at which new brands and flavors of e-cigarettes are emerging and apparently thriving, with the lack of regulation. According to a recently released report published in the journal Tobacco Control, there are as many as 10 new brands of e-cigarettes and 240 new flavors emerging every month. The researchers scoured English-language websites that marketed e-cigarettes over the course of two time periods: May 2012 to August 2012 and December 2013 to January 2014. They counted older and newer brands as well as models, eGos (larger e-cigs with a removable tank), mods (customizable e-cigs), flavors, nicotine strengths, ingredients, and product claims. During the first time period, they found 288 cigarette brands, however, 37 of them had disappeared when they searched again. During the second time period, another 215 brands appeared. Overall, there were 466 new brands by the end of the study. More astoundingly, there were 7,764 new and unique flavors, including tobacco and menthol. “

The North Carolina Alliance for Health works to improve the health of North Carolinians by advocating policies that promote wellness and reduce the impact of tobacco use and obesity.
The alarming increase in youth exposure to e-cigarette ads and the fast pace at which new flavors are being introduced strongly underscores why the FDA needs to quickly finalize the proposed rule within the next six to 12 months. NCAH strongly encourages the FDA to immediately develop follow-up regulations that close gaps in the proposed rule by restricting marketing and flavors that appeal to kids. In addition, there are many restrictions that apply to cigarettes and smokeless tobacco which the FDA should extend to newly covered tobacco products to provide a consistent prevention message and maximize immediate benefits to public health. For example, the proposal does not include requirements related to: minimum package sizes, prohibition on breaking packages by retailers, prohibition on tobacco brand names on non-tobacco products, prohibition on brand name sponsorship of sporting and cultural events. These are measures that are likely to help reduce access to these products, and therefore likely to help prevent young people from starting to use these addictive products.

The urgent need to address these three major concerns through FDA rules is demonstrated by the following preliminary analysis of the 2013 North Carolina Youth Tobacco Survey (NC YTS) which was shared by the NC Division of Public Health upon request.

Although we are encouraged that the current cigarette smoking rates among high school students decreased from 15.5 percent in 2011 to 13.5 percent in 2013, NCAH members and partners are deeply concerned that the overall current use of any tobacco product increased from 22.5 percent in 2011 to 24.5 percent in 2013. Given that North Carolina has seen reductions in tobacco use among our youth over the past decade, these are alarming statistics that call for urgent action.

In addition to traditional tobacco products, North Carolina youth are using a wide variety of emerging tobacco products, including flavored products, electronic cigarettes, and hookahs. These emerging products are widely available in fruit and candy flavors which are very appealing to the youth. Even more concerning is the data on dual users – students who are using two or more tobacco products. The statistics provided below regarding the emerging products are highly concerning and calls for immediate action.

**Flavored Cigarettes:**
- Nearly 5.5 percent of high school students reported currently using flavored cigarettes
- 94.2 percent of high school students who currently use flavored cigarettes also use at least one other tobacco product
- 6.6 percent of high school students reported that they are considering using flavored cigarettes in the next year

**Flavored Little Cigars**
- 4.6 percent of high school students currently use flavored little cigars
- 95.5 percent of high school students who currently use flavored little cigars also use at least one other tobacco product
- 6.1 percent of high school students are considering using flavored little cigars next year

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E-cigarettes
- **7.7 percent of high school students currently use e-cigarette compared to 1.7 percent in 2011; this is an increase of 350 percent in just two years.**
  - E-cigarette use is high among male students
  - 11th-12th graders reported a higher percentage of students currently using e-cigarettes than other high school grades
  - White students reported current e-cigarette use at a higher rate than other race and ethnicities
- 79.6 percent of high school students who currently use e-cigarettes also use at least one other tobacco product
- 10.0 percent of high school students reported that they are considering using e-cigarettes in the next year; this rate is as high as 11.6 percent among 12th graders
  - 2.7 percent of high school students who have never tried a cigarette are considering using e-cigarettes in the next year; what is even more concerning is that 3.6 percent of 10th graders who have never tried a cigarette are considering using e-cigarettes
- A point to note when looking at data on e-cigarettes: Researchers studying this issue at Wake Forest University tell us these rates likely under-report the actual use because of the way the question was worded and the fact that the nomenclature/means of identifying these products is rapidly evolving, especially for young people.

Hookah or waterpipe
- 6.1 percent of high school students are currently using hookah or waterpipe compared to 3.6 percent in 2011
- 88.4 percent of high school students who are currently using hookah or waterpipe also reported using at least one other tobacco product
- 10.7 percent of high school students reported that they are considering using hookah or waterpipe in the next year; this rate is as high as 15.5 percent among 12th graders

Multiple tobacco products
- 19.1 percent of high school students reported using two or more tobacco products
  - Male students reported a higher percentage of students using multiple products
  - Percentage of students using multiple products was highest among 12th graders, compared to other high school grades
  - White students reported a higher percent of students using multiple products

Cigarette smoking among North Carolina middle school and high school students has significantly decreased over the past decade due to important public health interventions at the state and federal levels. However, according to the 2013 preliminary analysis, 20.1 percent of middle school and 23.1 percent of high school never smokers are susceptible to tobacco use in the near future. This is critically important since the US Surgeon General’s office reports that if young people can remain free of tobacco until age 18, most will never start smoking. We urge the FDA to continue supporting applied research to prevent and reduce nicotine addiction. However, the dramatic increase in the prevalence of youth initiation of a new generation of tobacco products, especially electronic cigarettes, little cigars, and hookah, is an alarming public health issue.

*The North Carolina Alliance for Health works to improve the health of North Carolinians by advocating policies that promote wellness and reduce the impact of tobacco use and obesity.*
For this reason, the members and partners of the North Carolina Alliance for Health urge the FDA to act swiftly, within a year or less, to help reverse the new trend of nicotine addiction among our youth and to stop the addiction, illness and other harms being caused by the current unregulated state of these products.

Thank you for the opportunity to submit comments on this important public health matter.

Sincerely,

Pam Seamans
Executive Director
North Carolina Alliance for Health


ii ibid

iii ibid
