August 7, 2014

Division of Dockets Management HFA-305 SUBMITTED VIA: Regulations.gov
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, RIN 0910-AG38

I write on behalf of the American Public Health Association, a diverse community of public health professionals who champion the health of all people and communities, to urge the Food and Drug Administration to significantly strengthen the proposed “deeming” rule, in accordance with its statutory mandate to protect the public’s health. APHA has long supported tobacco prevention through a range of efforts including advertising and marketing controls,1,2 and regulation of tobacco products by FDA.3,4 We are pleased that we now have the opportunity to provide comments on the proposed deeming rule that has the potential to accelerate the nation’s progress toward eliminating the harmful effects of tobacco.

PURPOSE OF TOBACCO CONTROL ACT & PUBLIC HEALTH STANDARD

I. DEEMING RULE SHOULD APPLY TO ALL PRODUCTS MEETING THE STATUTORY DEFINITION OF A “TOBACCO PRODUCT,” WITHOUT EXCEPTION

APHA sees no justification for a “premium cigar” regulatory exemption. It is in the interest of public health to include all tobacco products because any

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3 American Public Health Association, Regulation of Tobacco Products by the Food and Drug Administration, policy statement 9412, adopted 1994.
exemption—particularly for a product as hazardous as cigars—would create a
dangerous precedent that might lead to other exemptions at a later point.

The FDA proposed deeming rule outlines the dangers of cigar smoking. These
dangers are not in doubt, despite what the cigar industry wants the public to
believe. The National Cancer Institute published a Tobacco Control Monograph
in 1998 that documented the cancer risk associated with cigar use, including
cancers of the lungs, larynx, oral cavity and esophagus.\(^5\) In addition, cigar
smokers are at increased risk of coronary heart disease and chronic obstructive
pulmonary disease\(^6,\,7\) and there are 5.2 estimated life-years lost due to cigar
smoking.\(^8\) Finally, tar, carbon monoxide and ammonia levels are higher in cigars
than cigarettes.

Given this evidence, along with other studies showing the growing use of cigars,
FDA must not provide an exemption for any cigar category, including premium
cigars. As shown by tobacco companies reformulating cigarettes in order to meet
the definition of a “little cigar”, although they are functionally used as cigarettes,
tobacco companies will use any exemption to undermine regulatory
intent in ways that harm public health.\(^10\)

II. FDA SHOULD ESTABLISH A PRODUCT STANDARD PROHIBITING
FLAVORS IN ALL TOBACCO PRODUCTS

FDA is not proposing to restrict the sale of flavored smokeless tobacco, cigars or
e-cigarettes. This is in contrast to how cigarettes are treated in the Tobacco
Control Act, except for menthol. FDA’s Parental Advisory on Flavored Tobacco
Products concluded that flavored tobacco products will: 1) appeal to kids; 2)
disguise the bad taste of tobacco; 3) be just as addictive as non-flavored tobacco
products; and 4) be just as harmful to one’s health as non-flavored tobacco
products.\(^11\) Flavored products are appealing to youth, as evidenced by the
marketing and flavors which make it easier to use a tobacco product.\(^12\)

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\(^8\) Steinberg MB, Delnevo CD. Tobacco Smoke by Any Other Name is Still as Deadly, 152 Annals Internal Med. 259, 259 (2010).


\(^11\) Food and Drug Administration. Parental Advisory on Flavored Tobacco Products (2013); available at [http://www.fda.gov/TobaccoProducts/ProtectingKidsFromTobacco/FlavoredTobacco/ucm183196.htm](http://www.fda.gov/TobaccoProducts/ProtectingKidsFromTobacco/FlavoredTobacco/ucm183196.htm).

Smokeless tobacco comes in a variety of flavors, including wintergreen, mint, cherry, berry, apple, peach and other similar flavors. In addition to the concern that these flavors will be appealing to kids, evidence suggests that adults are using these products at a fairly high rate. In one study of adult smokeless tobacco users who were enrolled in a cessation study, over half were currently using a mint-flavored product (59 percent) and about the same percentage (58 percent) had initiated use with such a product. Flavored smokeless tobacco product sales increased 72 percent between 2005 and 2011, and during that same time period, flavored products accounted for over half of all moist snuff sales each year.

Flavored cigars are perhaps even more popular than other forms of flavored products among individuals who use the general category of products. Between 2008 and 2011, 75 percent of the growth in cigar sales was attributed to the category of flavored cigars. Data suggest that male youth are using cigars at a similar rate as cigarettes—both are approximately 16 percent. A more in-depth analysis of data from the Florida Youth Tobacco Survey suggests that almost 69 percent of high school cigar smokers use flavored cigars. Youth are not the only ones using flavored cigars. Other data from the Centers for Disease Control and Prevention suggests that smokers of all ages use flavored cigars, although the prevalence decreases from 57 percent among 18-24 year-olds to 13 percent among smokers over age 65. More troubling, however, is the evidence suggesting that underserved groups, including Hispanics and LGBT groups, are more likely to use flavored products compared to non-Hispanics and heterosexual cigar smokers, respectively.

Recent findings by Couch, Chaffee, Essex and Walsh from the University of California San Francisco School of Dentistry suggest that high school students are using flavored e-cigarettes as well (unpublished work – please see attached document). In their study of 210 rural male youth in California, the prevalence of e-cigarette use was 13 percent compared to an 18 percent prevalence of smokeless tobacco, 9 percent prevalence of cigar products, and 6 percent prevalence of cigarette use. All of the participants who used e-cigarettes reported using a flavored product. In addition, 76 percent of smokeless tobacco users and 68 percent of cigar product smokers reported using a flavored product.

14 Delnevo et al.
Given this evidence, FDA must prohibit sales of all flavored tobacco products, as well as flavored electronic cigarettes.

III. FDA MUST STRENGTHEN THE PROPOSED WARNING LABEL REQUIREMENTS FOR NEWLY-DEEMED PRODUCTS

FDA must require warning labels for all tobacco products, including cigars (and premium cigars), hookah and e-cigarettes. Moreover, dissolvable tobacco products should be treated like smokeless tobacco products when regulating warning labels. While the proposed rule would mandate a health warning about the addictiveness of nicotine for all nicotine-containing tobacco products, it does not go far enough. Graphic warning labels are not being proposed and rotating warnings are not required for most of the newly deemed products.

The health warnings on cigar products and advertising would only address four health risks. The four to be rotated include the following risks: 1) cancer of the mouth and throat; 2) lung cancer and heart disease; 3) lung cancer and heart disease from secondhand smoke; and 4) cigars are not a safe alternative to cigarettes. But, the health warning that tobacco increases the risk of “infertility, stillbirth and low birth weight” is not being mandated. FDA states that they are “not aware of studies specifically linking cigars to these reproductive effects.” However, the report *U.S. Surgeon General, The Health Consequences of Smoking – 50 Years of Progress* devotes an entire chapter to the health effects of nicotine, including the effects on fetal development. The report documents that nicotine crosses the placenta and concentrates in the fetus. Additionally, nicotine constricts vessels and thus limits the amount of nutrients and oxygen delivered to the fetus.

FDA’s proposed warnings should be mandated for all tobacco products, including premium cigars and e-cigarettes. The proposed warning labels for cigars should not include a premium cigar exemption, and cigar warnings should include the warning related to reproductive risks of cigars.

Additionally, FDA should clarify that the required warnings must be prominently displayed on all websites including social media websites that advertise or sell tobacco products. In the proposed rule, the term “advertisement” is not defined, which could lead to confusion about whether such websites are covered by the rule. Given the importance of websites and social media in promoting tobacco product use, this should be clarified.

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IV. FDA SHOULD EXTEND MARKETING AND SALES RESTRICTIONS APPLICABLE TO CIGARETTES AND SMOKELESS TOBACCO TO ALL TOBACCO PRODUCTS

The proposed FDA rule does not include some of the important sales and marketing restrictions that currently apply to cigarettes. We will first address the sales issues. Under the Tobacco Control Act, self-service access to cigarettes and smokeless tobacco is prohibited. FDA is not including a proposal to ban self-service displays of other tobacco products. There is no public health rationale for maintaining self-service displays in retail stores. Without such a ban, displays of cigars and e-cigarettes with candy and fruit flavors could still be placed next to real candy and other items that appeal to kids in retail stores. The second sales restriction that is not included in the proposed rule, but should be, is one that would require a minimum pack size. By requiring a minimum pack size, FDA would prevent the sale of inexpensive single cigars, as well as other products, that appeal to kids. Research demonstrates that increasing the price of tobacco reduces youth initiation and adult consumption rates. A minimum pack size has the consequence of raising the price of tobacco. An additional benefit of a larger pack versus a single use is the increased surface area, which is necessary for health warnings and ingredient disclosures.

Another related topic is internet sales. The FDA proposed rule does not require any age verification for internet sales. Because this would be a difficult regulation to enforce, FDA should prohibit internet sales of the deemed products. If that is not feasible, then at the very minimum, FDA should adopt age verification procedures for internet sellers, similar to the procedures in place for cigarettes and smokeless tobacco products.

The FDA proposed rule does not extend important marketing restrictions that apply to cigarettes and smokeless tobacco. Such restrictions are important methods of preventing youth initiation. These include bans on tobacco product brand and trade names of non-tobacco products (e.g., clothing, coolers etc.) and sponsorships of sporting and cultural events. An additional requirement is that companies must notify the FDA when advertising in a non-traditional venue.

FDA should apply the same sales and marketing restrictions that currently apply to cigarettes and smokeless tobacco. There is no public health rationale to not extend bans on self-service displays, require minimum pack sizes, require age verification for internet sales and ban tobacco product sponsorships.

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V. FDA MUST DEVELOP A MORE COHERENT REGULATORY FRAMEWORK FOR REGULATING ELECTRONIC NICOTINE DELIVERING SYSTEMS, WITH A FOCUS ON PROTECTING THE PUBLIC’S HEALTH

The proposed rule refers to the “continuum of nicotine-delivering products that pose differing level of risk to the individual”, and it specifically requests comment on “the potential benefits associated with e-cigarettes.” While such products may potentially offer public health benefits, the history of tobacco regulation and emerging evidence regarding current use of e-cigarettes suggest reasons for caution. FDA should develop a coherent regulatory framework that, as set forward in the Tobacco Control Act, places the burden of proof on product manufacturers to establish the validity of any health-related claims and to prove that the sale of e-cigarettes or other novel products would be “appropriate for the protection of public health.”

FDA’s regulatory approach must keep the history of the tobacco industry in mind. As established in United States v. Philip Morris USA, for nearly half a century all of the major tobacco companies “vigorously—and falsely—denied the existence of any adverse health effects from smoking [and] mounted a coordinated, well-financed, sophisticated public relations campaign to attach and distort the scientific evidence demonstrating the relationship between smoking and disease.” At the same time, they marketed products such as “light” and “low tar” cigarettes in order to alleviate health concerns, despite their own internal knowledge that these products did not reduce the health risks of smoking. The public health community and government agencies joined the tobacco industry in endorsing a “harm reduction” approach, encouraging smokers who could not quit to switch to supposedly less harmful products. This ultimately proved to be deeply misguided and harmful to the public’s health.

This history does not mean that the ongoing quest for less harmful tobacco products is doomed to failure, but it does suggest a need for caution, particularly when the leading cigarette companies including Altria/Philip Morris, R.J. Reynolds and Lorillard are involved. Given their history of engaging in a pattern of racketeering conduct, these companies should be held to a rigorous burden of proof. As Congress stated, “Unless tobacco products that purport to reduce the risks to the public of tobacco use actually reduce such risks, those products can cause substantial risk to the public health…..” The fact that all three of these companies have now invested heavily in e-cigarettes while not in any way

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21 79 Fed. Reg. at 23147 (emphasis added)
25 Tobacco Control Act § 2(37)
curtailing their promotion of conventional cigarettes heightens the need for vigilance.

The Tobacco Control Act calls for a population-level analysis that takes into account the health of the population as a whole, including users and non-users of tobacco products. Even products that are less harmful than conventional tobacco products on an individual level may still increase public health harms if, for example, they encourage non-users to start using tobacco products which can lead to lifelong nicotine addiction, or they promote dual use in place of tobacco cessation. Importantly, because duration of cigarette use is correlated with premature mortality much more closely than the intensity of such use, “[u]se of electronic cigarettes by cigarette smokers to cut down on the number of cigarettes smoked per day is likely to have much smaller beneficial effects on overall survival compared with quitting smoking completely.”\(^{26}\) Thus, if electronic nicotine delivery systems, also known as ENDS, use leads to stable patterns of dual use alongside combustible tobacco products, they may well increase population level harms. Although the evidence is not yet conclusive, “the high rates of use of both ENDS and conventional cigarettes among current ENDS users suggest that many are using them as a way to satisfy their nicotine addiction in venues where smoking is not allowed rather than as a means to quit smoking entirely.”\(^{27}\)

As FDA develops its regulatory system for ENDS, we urge it to keep these concerns in mind. FDA’s sole priority should be to protect the public’s health. Crucially, to the extent ENDS manufacturers believe that their products are effective for smoking cessation, there is already a pathway through which they can seek approval to make such claims. Although the *Sottera v. FDA* decision provided that “customarily marketed” e-cigarettes should be regulated as tobacco products, it also emphasized that e-cigarettes “marketed for therapeutic purposes”—which would include smoking cessation—are subject to FDA’s drug and/or drug-delivery device provisions. Before making any direct or indirect smoking cessation claims, product manufacturers should be required to prove the validity of such claims under FDCA’s drug and drug-delivery device provision. Until they do so, FDA should prohibit ENDS manufacturers from making unsupported smoking cessation claims. There is considerable evidence that FDA has thus far failed to do so.\(^ {28,29}\)

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A. FDA SHOULD REQUIRE CHILD-PROOF PACKAGING OF E-LIQUIDS CONTAINING NICOTINE

The FDA’s proposed rule does not address concerns about nicotine poisoning that could be caused by the “e-liquids” used in conjunction with ENDS. This concern is particularly acute for children, for whom nicotine, especially in the concentrations present in e-liquids, is severely neurotoxic. Already, CDC has reported a dramatic increase in calls to poison control associated with ENDS. Indeed, the proposed rule notes that 51 percent of calls to poison centers related to e-cigarettes have involved children under the age of 6. FDA should address this concern by requiring e-liquids containing nicotine to be sold only in childproof packaging.

B. FDA SHOULD REGULATE THE COMPONENTS AND PARTS OF ENDS, REGARDLESS OF WHETHER THE DELIVERY SYSTEM AND NICOTINE ARE SOLD TOGETHER OR SEPARATELY

FDA’s proposed rule creates confusion by providing that only ENDS components that contain nicotine are subject to the rule’s regulatory requirements. This creates an incentive for manufacturers to separate nicotine-containing components from non-nicotine-containing components in order to evade regulatory requirements. This would severely and unnecessarily complicate FDA’s regulatory and enforcement efforts. For example, it would make it possible for minors under the age of 18 to legally purchase ENDS delivery devices, so long as they did not contain the e-liquid. Those minors could then attempt to obtain the e-liquid separately from another source (e.g., online, where the proposed FDA rule does not require age verification). The separate sale of nicotine and non-nicotine components would allow easier access to minors, increase the risk of nicotine poisoning, and make it difficult for FDA to monitor how these products are used in practice. It would also increase the likelihood that ENDS products would be used for the delivery of other illegal drugs.

FDA’s rule should instead regulate both ENDS delivery systems and e-liquids containing nicotine, whether they are sold together or separately. As the proposed rule implicitly recognizes by extending its authority, though not its regulations, to ENDS components, there is no legal barrier to FDA regulating all components and parts of ENDS.

C. FDA’S PROPOSED SYSTEM FOR PREMARKET REVIEW OF ENDS WILL FAIL TO PROTECT THE PUBLIC HEALTH AND MUST BE AMENDED

The proposals regarding the premarket regulation of ENDS are deeply concerning. As stated above, the law requires product manufacturers to prove that the sale of their products would be “appropriate for the protection of the public health.” Given the history of the tobacco industry’s introduction of new products that purported to—but did not—provide public health benefits, FDA should exercise appropriate caution in its review of new products.

The proposed rule suggests a two-year delay before FDA will enforce the law’s requirement for manufacturers of “new” products—those products introduced after Feb. 15, 2007—to file a substantial equivalence application or a premarket tobacco product application. FDA is further proposing that manufacturers will be able to continue selling such products unless and until FDA rejects its submission, which could be years later. These delays are uncalled for and could be dangerous to public health. Most obviously, this structure would incentivize manufacturers to file an SE application or PMTA at the last possible minute, in order to maximize the time before FDA enforcement would begin. This is what occurred with SE applications for cigarettes, where 3,491 such applications were filed in March 2011 alone just prior to the deadline after which new products could not be marketed while under review, causing a massive backlog that FDA is still working to clear.

The initial two-year delay is also unwarranted. Since the Sottera decision in December 2010, if not before, ENDS manufacturers have known that their products were subject to regulation under FDA’s tobacco regulatory authority. In April 2011, more than three years ago, FDA issued a stakeholder letter indicating its intent to regulate ENDS and specifically noting the requirement of premarket review in the Tobacco Control Act. FDA’s three-year delay before issuing such a rule has allowed a “wild, wild west” marketing culture to develop, with manufacturers aiming to get their products as widely distributed as possible before any FDA regulation. Given this extensive prior notice and the harms already caused by FDA’s delayed action, an additional two-year delay, plus the time needed to review applications, is excessive.

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The proposed rule appears to suggest that a two-year delay is appropriate because parallel requirements for cigarettes and smokeless tobacco did not take effect until two years after the Tobacco Control Act was passed. This conclusion is illogical. The initial two-year timeframe provided time for FDA to establish the Center for Tobacco Products and for manufacturers to prepare for, what were arguably unexpected, FDA regulatory requirements. At present, CTP is fully operational and, as shown above, ENDS manufacturers cannot reasonably argue that regulation was unexpected. Nothing in the law requires FDA to apply the same two-year delay to ENDS or other newly-deemed products. Such a delay will only perpetuate the “wild, wild west” marketing culture that both CTP Director Zeller and FDA Commissioner Hamburg have criticized. FDA’s proposed rule contains substantial evidence indicating why regulation of ENDS is appropriate; this same evidence militates against any unnecessary delays.

Based on FDA’s own estimates of the time needed by manufactures to comply with the premarket application requirements, a compliance period of 180 days is sufficient and there is no justification for delaying the effective date for the submission of SE applications or PMTA’s by more than 12 months. Moreover, FDA should determine how to incentivize early submission, rather than reward delay.

Finally, FDA should ensure that ENDS manufacturers do not abuse the SE pathway, as cigarette companies have done. The law clearly intended for PMTA to be the primary pathway for approval of new tobacco products. Expedited preliminary review of SE applications is needed to ensure that ENDS companies cannot seek to avoid or delay regulatory requirements by filing meritless SE reports.

VI. FDA’S REGULATORY IMPACT ANALYSIS IS DEEPLY FLAWED

In the regulatory impact analysis that accompanies the proposed rule, FDA significantly discounts the benefits of the rule by relying on the concept of “lost consumer surplus.” Under RIA’s flawed methodology, the benefits resulting from tobacco cessation are reduced by 70 percent to account for the “lost pleasure” experienced when people stop using tobacco.

Although lost consumer surplus is a well-established economic concept, it has no appropriate application to this particular situation. Indeed, Dr. Jonathan Gruber, whose articles FDA staff economists relied upon to justify their conclusions, recently stated that FDA’s use of the consumer surplus model in the context of...
FDA’s proposed rule was “a misapplication of my work.” According to Reuters, Gruber stated that “the fact that a majority of smokers pick up the habit as teenagers and become addicted before they are fully aware of the consequences, meant the FDA was wrong to invoke the ‘consumer surplus’ concept.”

As Gruber suggests, the fact that the initial decision to smoke is most often made by minors who then continue smoking out of addiction rather than out of desire makes the consumer surplus model inapposite. Moreover, application of the consumer surplus model is also misguided because when consumers respond to the information provided by health warnings and choose to quit using tobacco products, they are making an informed and deliberate choice—indeed, an extremely difficult choice, given the addictiveness of nicotine. In such a situation, the decision to quit using tobacco is, in and of itself, recognition that the consumer is not obtaining any consumer surplus from the purchase of tobacco products.

Smoking is addictive and harmful, and promoting smoking cessation is a central part of the mission assigned to FDA’s Center for Tobacco Products by Congress. Suggesting that consumers in any way “lose out” by quitting smoking is contrary to both the lived experience of former smokers, most of whom required multiple attempts to successfully quit, and the basic purpose of FDA’s tobacco regulatory mission.

VII. FDA SHOULD WORK TO FINALIZE AND ENFORCE THE RULE AS QUICKLY AS POSSIBLE AND WITHOUT FURTHER DELAY

More than three years passed between the time that FDA indicated its intent to issue a deeming rule and the release of this proposed rule—an unacceptable lapse in time. In September 2013, after waiting more than two years for the promised deeming rule, APHA joined with other local, state and national public health voices in submitting a citizens’ petition to FDA asking it to regulate all products meeting the Tobacco Control Act’s definition of “tobacco products.” That citizens’ petition included a substantial amount of supporting evidence, and is included as an attachment to these comments.

As stated in the petition: “Continuing to delay action provides the tobacco industry with wide reign in designing, marketing and selling tobacco products that entice and addict young people through many of the tactics long-forbidden with respect to cigarettes. The public health community is unwilling to tolerate continued delay in protecting public health, a sentiment that is shared by members of both houses of Congress.”

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APHA again reinforces its position that regulation of all tobacco products is long overdue, and such regulations must be put in place as quickly as possible in order to protect the public’s health.

We appreciate the opportunity to provide comments on the deeming of tobacco products subject to FDA’s regulatory authority as it is a critical step in actualizing the full potential of the Tobacco Control Act and in preventing tobacco-related deaths and diseases.

Sincerely,

Georges C. Benjamin, MD
Executive Director