FDA should revise its new guidance on listing of ingredients in tobacco products to require disclosure of all ingredients that can become toxic during normal use

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FDA's April 2018 revised guidance for industry on the requirements for submitting listings of tobacco product ingredients ***is inconsistent with its mandate to protect the public health*** because by narrowing the definition of "tobacco products" to exclude certain components or parts, it ***allows manufacturers to not disclose ingredients and materials of some tobacco products that have the potential to harm consumers during normal use.***

FDA's guidance necessarily is based on terms that have been defined in the Family Smoking Prevention and Tobacco Control Act, the Federal Food, Drug, and Cosmetic Act, and FDA's final rule, 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 ("the Deeming Rule," published in May 2016[1]). Although the definition of a key term, "components or parts," is clearly stated in these documents, and although the deeming rule provided explicit examples of items that would be considered "components or parts," in the April 2018 revised guidance on listing of tobacco product ingredients, FDA stated it would not enforce the ingredient listing submission requirement with respect to certain components and parts that the deeming rule explicitly said should be subject to this automatic provision, in particular ENDS components including coils, atomizers, cartomizers, digital displays, programmable software, batteries, and glass or plastic vials for e-liquids; waterpipe/hookah components including charcoal, bowls, valves, hoses, and heads; and cigar components including tips, mouthpieces, filters, and wrapping or tubes for single cigars.

1. Definitions matter -- all components and parts should be subject to the ingredient listing requirements

The guidance is intended to assist persons making tobacco product ingredient submissions to the FDA to comply with Section 904(a)(1) of the Tobacco Control Act. Section 904(a)(1) requires tobacco product manufacturers and importers to submit a listing of all ingredients, including tobacco, substances, compounds, and additives, that are added by the manufacturer to the tobacco, paper, filter, *or other part of each tobacco product.* The guidance provides that FDA intends to enforce the ingredients submission requirements of section

[1] 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 (81 FR 28974, May 10, 2016)

904(a)(1) with respect to all "finished tobacco products," including those regulated as a result of the deeming rule (e.g., e-cigarettes, cigars, hookah).

"Additive" means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical." (Tobacco Control Act section 900(1))

"Finished tobacco product" is defined in the guidance to mean ***"a tobacco product, including all components and parts***, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits)."

"Tobacco product" is defined as "any product made or derived from tobacco that is intended for human consumption, ***including any component, part, or accessory of a tobacco product***…" (Section 201(rr) of the FFD&C Act; 21 CFR 1140.3)

"Accessory" means "any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or
(2) is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but
    i. solely controls moisture and/or temperature of a stored product; or
    ii. solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

"Component or part" means "any software or assembly of materials intended or reasonably expected:

(1) to alter or affect the tobacco product's performance, composition, constituents, or characteristics; or
(2) to be used with or for the human consumption of a tobacco product.

Component or part excludes anything that is an accessory of a tobacco product. (21 CFR 1140.3)

At the time the Tobacco Control Act was enacted in June 2009, FDA's regulatory authority extended only to cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco. Therefore, the guidance for industry on listing of ingredients in tobacco products that FDA published in November 2009 applied only to these products.

In May 2016 the final "Deeming Rule" was published that extended FDA's authority to all other tobacco products that meet the statutory definition of "tobacco product" set forth in

section 201(rr) of the FD&C Act. Examples of currently marketed products that the Deeming Rule made subject of FDA's tobacco authorities include: cigars; pipe tobacco; hookah; electronic nicotine delivery systems (ENDS) including e-cigarettes, e-hookah, e-cigars, vape pens, vaporizers, electronic pipes, and nicotine-containing liquids including e-liquids used with ENDS; nicotine gel, and certain dissolvable nicotine products, among other products. Although the definition of "tobacco product" explicitly includes accessories, the Deeming Rule excludes accessories of newly deemed tobacco products from FDA's tobacco product authorities.

In late December 2016 FDA published a revised guidance (dated "January 2017") on listing of ingredients in tobacco products clarifying that as a result of the Deeming Rule, all newly deemed products that meet the statutory definition of "tobacco product", except accessories, are subject to the FDA's tobacco product authorities, including the section 904(1) ingredients disclosure requirements. The January 2017 revised guidance used the same definitions for "tobacco product," "finished tobacco product," "additive," "accessory," and "component or part" as was adopted in the April 2018 guidance.

Importantly, in describing its compliance policy for the ingredients submission requirements, the 2017 guidance stated:

> Components and parts that are sold separately from other tobacco products are also finished tobacco products if they are sold in final packaging intended for consumer use. FDA intends to enforce the requirements for submission of ingredient information under section 904(a)(1) with respect to such products. ***Examples of components and parts that are sold or may be sold as finished tobacco products include pipe tobacco filler, filter tubes, e-cigarette batteries, and e-liquids, whether sold separately to consumers or as part of kits.*** (emphasis added, 2017 guidance, page 6)

In other words, the 2017 guidance aligned FDA's enforcement policy for newly deemed tobacco products with the existing policy for cigarettes, cigarette tobacco, roll-your-own, and smokeless tobacco, and made clear that in keeping with the definition of "tobacco products" and the provisions of section 904(a)(1). ***Manufacturers were required to submit ingredient information for all components and parts*** that are sold as finished tobacco products.

However, in the April 2018 revised guidance FDA narrowed the types of finished products it intends to include under the section 904(a)(1) enforcement policy. The April 2018 revised guidance states that FDA intends to enforce the ingredient listing submission requirement ***only with respect to those components or parts:***

(1) Made or derived from tobacco, or
(2) Containing ingredients that are burned, aerosolized or ingested during tobacco product use.

FDA explained that it "intends to focus on components or parts made or derived from tobacco, or containing ingredients that are burned, aerosolized or ingested during tobacco product use because *we believe these components and parts of a finished tobacco product are*

generally the most important in determining the constituents to which users are exposed." (emphasis added, April 2018 guidance, p. 7) FDA acknowledges that "the ingredients of other components and parts can also be important in determining the public health impact of tobacco products," but rationalizes that FDA will receive ingredient information for these other components and parts during the premarket review of finished tobacco products (e.g., in PMTAs or Substantial Equivalence reviews). FDA said that if they determine that "additional information is helpful to protect the public health, the Agency may reconsider this compliance policy."

2. FDA's new compliance policy for the ingredients submission requirements does not protect the public health

FDA's new compliance policy only requires submission of ingredients listings for components and parts of tobacco products that contain ingredients "*that are burned, aerosolized or ingested during tobacco product use."* Examples of components or parts that would be excluded under FDA's new enforcement policy include: electrical components such as batteries, charging systems, circuit boards, wiring, and connectors; system software; cartomizers; coils; wicks; tanks; mouthpieces; pipes; waterpipes; hoses; bowls; charcoal; and cigarette filter that does not contain any ingredient that is burned, aerosolized, or ingested during tobacco use.

Ingredients in many of the components and parts of tobacco products that would be excluded from enforcement under this new policy may affect the toxicity of those products. Therefore, FDA should require ingredient and materials disclosure for any part of a tobacco product that comes into contact with the portions of the product that are consumed during normal use. This would include the containers e-liquids are stored in, cartomizers, coils, wicks, tanks, mouthpieces, pipes, hoses, bowls, charcoal and filters. These components can make significant contributions to the chemistry and toxicity of the portion of the product that is consumed.

For example, the toxin bisphenol A is known to leach from polycarbonate plastics, epoxy resins and polyvinylchloride plastics into water[2,3] and other consumer products[4] and the amount that is released increases with temperature[2]. If e-cigarette tanks and mouthpieces were made of a plastic containing bisphenol A or another toxin, the elevated temperatures would be expected to increase the transfer of the toxin into the aerosol.

Another way in which the materials and ingredients in tobacco products can affect the toxicity of tobacco products is through surface catalysis in e-cigarettes and heated tobacco products (also known as "heat-not-burn" products). Surface, or heterogeneous, catalysis is the acceleration of a chemical reaction by a catalyst when the reactant and the catalyst are in different physical phases. Through surface catalysis, the chemical composition and physical

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[2] Krishnan AV, Stathis P, Permuth SF, Tokes L, Feldman D. Bisphenol-a: An estrogenic substance is released from polycarbonate flasks during autoclaving. Endocrinology. 1993 Jun;132(6):2279-86.

[3] Le HH, Carlson EM, Chua JP, Belcher SM. Bisphenol a is released from polycarbonate drinking bottles and mimics the neurotoxic actions of estrogen in developing cerebellar neurons. Toxicol Lett. 2008 Jan 30;176(2):149-56.

[4] Mercogliano R, Santonicola S. Investigation on bisphenol a levels in human milk and dairy supply chain: A review. Food Chem Toxicol. 2018 Apr;114:98-107.

structure of coils, wicks and other heating and heat-adjacent surfaces can affect the chemistry of the aerosols produced by e-cigarettes and heated tobacco products.[5] The tobacco industry has studied and experimented with surface catalysis[6,7,8] and used it in the design of heaters for heated tobacco products[9] in the past, so it is reasonable to assume that this type of chemistry may be used in the design of future devices. Thus, it is important that the composition and chemistry of all surfaces in contact with the product to be consumed be disclosed.

The constituents of hookah smoke aerosol contain similar chemicals compared with cigarette smoke, many of which are known to be harmful to cardiovascular health, including carbon monoxide, polycyclic aromatic hydrocarbons, particulate matter, oxidants and inflammatory cytokines, heavy metals, phenols, and volatile organic compounds.[10] Of particular concern, ***the burning charcoal briquettes are a unique source of toxicant emissions specific to hookah smoking. Therefore, it is vitally important for FDA to require manufacturers to submit the listing of ingredients in hookah charcoal. FDA should not make an exception for these components of hookah.***

In addition to disclosing the composition of components such as coils and charcoal, FDA should *require* that manufacturers provide documentation of purity that enables FDA to trace the primary source. While FDA does "request" for each single chemical substance (at page 10 of the guidance) and for complex purchased ingredients (at page 12 of the guidance) that manufacturers "provide the quality (e.g., percent purity, a published standard)" of the ingredient or complex ingredient, FDA should make this information mandatory so it can determine if toxic elements as impurities of the ingredients or toxic preservatives are present that might leach out or otherwise harm consumers during use.

Any parts or components of tobacco products (including e-liquids, plastics, or metal components), especially those that come in contact with the user's mouth, should at a *bare minimum* meet FDA's Generally Recognized as Safe (GRAS) standards. We emphasize that these are just a starting point, not a ceiling, and agree with FDA's statement in the Deeming Rule that GRAS is not relevant to establish a tobacco product is appropriate for the protection of the public health with regard to inhaled substances as required by the Tobacco Control Act:

> Section 910 of the FD&C Act requires FDA to evaluate the new tobacco product as a whole to determine whether the authorization of marketing of the product is appropriate for the protection of the public health. In addition, ***we note that GRAS***

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[5] Chorkendorff I, Niemantsverdriet J. Concepts of modern catalysis and kinetics. Weinheim, Germany: Wiley, VHC; 2017.

[6] Perry L, Banerjee C, Jackson T. Records Rj Reynold. Joint technology literature review: Catalysis. 8/10/2006 2006. https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/sqnk0225.

[7] Hajaligol M. Morris Philip. Monthly report for 910100. 01/21/1991 1991. https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/rmmk0128.

[8] Dyakonov A. Lorillard. A study of the mechanisms of co reactions on silver b637. 9/22/1998 1998. https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/lnby0069.

[9] Cook CJ, Polo A, Zoller M, Waltermire BE, Smith S, inventors; R J Reynolds Tobacco Co assignee. Smokeless method and article utilizing catalytic heat source for controlling products of combustion. U.S.A. 1996.

[10] Rezk-Hanna M, Benowitz NL, Cardiovascular Effects of Hookah Smoking: Potential Implications for Cardiovascular Risk, *Nicotine & Tobacco Research*, 2018, 1–11 https://doi-org.ucsf.idm.oclc.org/10.1093/ntr/nty065 (Advanced access publication April 5, 2018)

> ***status for a food additive does not mean that the substance is GRAS when inhaled, since GRAS status does not take inhalation toxicity into account and applies only to intended uses that may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food*** (section 201(s) of the FD&C Act.) [Emphasis added].[11]

In addition to the direct health effects contributed through how materials are liberated from device components into the smoke, aerosol, or other ingested substrate, the potentially significant environmental health consequences of these products should also be taken into account.[12] For example, an e-cigarette device with a battery more prone to malfunction could have direct health consequences for the consumer (i.e., batteries blowing up in users' faces, leakage of battery acid on skin, e-cigarette users relapsing to smoking cigarettes if the e-device malfunctions)[13] as well as may create additional unnecessary and significant electronic-waste (e-waste) if product robustness standards are low.[14] As new electronic device components require vastly more and different resources than traditional tobacco products, in terms of the hazards involved in manufacturing, use, and disposal, attention to the significant long-lasting environmental health consequences of these products, and the populations subjected to their toxins before and after use, disclosing the contents of component parts will facilitate regulation to reduce the significant environmental and health harms these products may pose to the public.[15] Ingredient transparency is especially important because actual data on e-cigarette waste is not currently available.

Disclosure of the ingredients and materials of tobacco products as described above will allow manufacturers, regulators and the public to correlate changes in the toxicity, addictiveness, or subjective qualities of the products with any changes or differences in materials and ingredients.

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[11] 81 FR at 29001-29002. 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 (81 FR 28974, May 10, 2016). Available at: https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf

[12] Lerner CA, Sundar IK, Watson RM, Elder A, Jones R, Done D, et al. Environmental health hazards of e-cigarettes and their components: Oxidants and copper in e-cigarette aerosols. Environmental Pollution. 2015 Mar;198:100–7.
Krause MJ, Townsend TG. Hazardous waste status of discarded electronic cigarettes. Waste Manag 2015;39:57–62.

[13] Patterson SB, Beckett AR, Lintner A, Leahey C, Greer A, Brevard SB, et al. A Novel Classification System for Injuries After Electronic Cigarette Explosions. J Burn Care Res. 2017 Feb;38(1):e95–100.

[14] Chang H. Research gaps related to the environmental impacts of electronic cigarettes. Tobacco Control. 2014 May;23(suppl 2):ii54–8. Fifty-eight million e-cigarette devices and components were sold in supermarkets and convenience stores in 2015 (Nielsen Data). Marynak KL, Gammon DG, Rogers T, Coats EM, Singh T, King BA. Sales of Nicotine-Containing Electronic Cigarette Products: United States, 2015. Am J Public Health. 2017 Mar 21;107(5):702–5.

[15] World Health Organization. Tobacco and its environmental impact: an overview [Internet]. 2017 [cited 2017 Sep 13]. Available from: http://www.who.int/tobacco/publications/environmental-impact-overview/en/. If the FDA required disclosure of the components in e-cigarettes, product robustness standards could be developed. The lack of data on the quantity of existing products and their differential effects on environmental health, could be remedied through requiring disclosure of these product aspects. Of the hundreds of millions of e-cigarettes so far sold in the US, so far no data on how these devices, including highly toxic and flammable lithium-ion batteries, are being disposed of. Chang H. Research gaps related to the environmental impacts of electronic cigarettes. Tobacco Control. 2014 May;23(suppl 2):ii54–8.

Finally, as we discussed in a comment submitted to this docket in November 2016[16] (attached), while FDA must maintain the confidentiality of "nonpublic trade secret or confidential commercial information," neither the FD&C Act, the Trade Secrets Act, nor the Freedom of Information Act requires FDA to conceal from the public information that is neither a trade secret nor confidential commercial information. Rather, FDA can and should make publicly available the identity of the product ingredients without revealing the blends or formulas, thereby respecting the laws' requirements by both protecting company trade secrets and protecting the public health by allowing consumers to know what they are consuming.

3. FDA's new compliance policy has no legal basis and contradicts explicit policies enunciated in the Deeming Rule

This new policy has no legal basis as it is not based on the statutory definitions of "tobacco product" and "components or parts" that are at the core of the section 904(a)(1) ingredients submission requirements. Indeed, many of the products that are now excluded from ingredients listing requirements were explicitly discussed in the Deeming Rule (81 FR 28974) and explicitly made subject to FDA's tobacco authorities.

Section VI of the Deeming Rule (starting at 81 FR 28974 at 29015) explains at length FDA's current compliance policy with respect to components and parts and the requirements that became effective with the Deeming Rule. FDA explained that the definition of "accessory" was deliberately structured "*to ensure that coils and charcoal are not encompassed by the definition of 'accessory'*". (81 FR 28974 at 29015) Since only accessories of newly deemed tobacco products are excluded from FDA's tobacco authority reach, this means that ***FDA specifically considered coils and charcoal to be components and parts that are subject to FDA's tobacco product authorities, including section 904(a)(1) ingredients listing requirements.***

FDA noted that the term "material" in the term "component or part" means an assembly of ingredients, including additives, and materials are assembled to form components and parts. In particular, FDA explained: "***A material could be considered the plastic in the mouthpiece of an ENDS*** containing multiple ingredients and additives assembled together to create a product." (81 FR 28974 at 29015)

Further, in determining whether software or an assembly of materials might be "intended or reasonably expected" to alter or affect the tobacco product's performance, composition, constituents, or characteristics or to be used with or for the human consumption of a tobacco product (i.e., in determining whether it is a "component or part"), FDA stated that it is not bound by the manufacturer's or distributor's subjective claims of intent. Rather, "FDA can consider the totality of the circumstances, including direct and circumstantial objective evidence, which encompasses a variety of factors such as circumstances surrounding the distribution of the product or the context in which it is sold… and sales data." (81 FR 28974 at 29015)

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[16] Lempert LK, Popova L et al. Listing of Ingredients in Tobacco Products – Revised Draft Guidance for Industry; Docket Number FDA-2009-D-0524 (November 28, 2016). Available at https://www.regulations.gov/document?D=FDA-2009-D-0524-0031, tracking number 1k0-8tan-dl14

In the Deeming Rule, FDA provided examples of "materials intended or reasonably expected to be used with or for the human consumption of a tobacco product" (i.e., are included in paragraph (2) in the definition of "components or parts" and therefore are subject to FDA's tobacco authorities, including the listing requirements). These include (but are not limited to): atomizers and cartomizers used with ENDS; water filtration base additives (including those which are flavored) used with waterpipe tobacco; and pouches or flavorings used with any of the newly deemed products. (81 FR 28974 at 29015) FDA also provided some examples of "materials intended or reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics" (i.e., are included in paragraph (1) in the definition of "components or parts" subject to the listing requirements). These include: the cellophane wrapping or plastic tube for a single cigar; and a glass or plastic vial container of e-liquid. (81 FR 28974 at 29015)

FDA explained that these examples are materials that are intended or reasonably expected to alter or affect the composition, constituents, or characteristics of a tobacco product. FDA pointed out, for example, that "***these materials often leach ingredients into the consumed product… with ENDS, there is the potential for substances to leach from the containing vial into the e-liquid and these leachates may be inhaled when the e-liquids are used as intended, posing additional health risks for consumers***." FDA also stated that the moisture level of a tobacco product and changes to that moisture level can significantly impact consumers' exposure to nicotine and other constituents, and menthol or other ingredients may have been applied to these materials that become incorporated into the consumer product that could have added effects. (81 FR 28974 at 29015) The potential toxicities and harms to human health described above and supported by scientific evidence further support FDA's examples and conclusions.

FDA provided a nonexhaustive list of examples of materials used with waterpipe tobacco that would be considered components and parts subject to its regulatory authorities, including the listing requirements: "flavor enhancers; hose cooling attachments; water filtration base additives (including those which are flavored); flavored hookah charcoals; and bowls, valves, hoses, and heads." (81 FR 28974 at 29016) FDA acknowledged comments it received explaining that combustion of charcoal or wood cinder used with waterpipe produces toxicants and may emit carcinogens, carbon monoxide, polycyclic aromatic hydrocarbons, and other cancer causing agents, and found that they are considered components or parts subject to tobacco regulations because that are intended or reasonably expected to alter the characteristics of the tobacco product and are used to maintain the combustion of waterpipe tobacco. (81 FR 28974 at 29019) As described above, further scientific evidence supports FDA's conclusion that these components and parts are capable of affecting the chemistry and toxicity of the product that is consumed.

In addition to its list of components and parts used with waterpipe tobacco, in the Deeming Rule FDA provided clarification and examples as to which objects used with e-cigarettes would be considered components and parts. FDA provided the following nonexhaustive list of examples of components and parts of ENDS (including e-cigarettes): "atomizers, flavors used or intended to be used with ENDS (with or without nicotine), e-liquid solvents, tanks and tank systems, batteries (with or without variable voltage), coils, cartomizers, digital display/lights to adjust settings, clearomisers, and programmable software." (81 FR 28974

at 29016) (Examples of items that FDA considered accessories that would be excluded from its tobacco product authorities included screwdrivers and lanyards.)

Regarding materials associated with cigars, FDA stated that in contrast to cigar tip cutters, holders, and ashtrays that are "accessories" not subject to FDA regulation, "removable tips, mouthpieces, and filters are all intended to be used by adult consumers in the human consumption of a tobacco [sic] and do not meet the definition of accessory, therefore, are included within the scope of this final rule." (81 FR 28974 at 29019) As described above, scientific evidence demonstrates that tips and mouthpieces may leach toxic chemicals that can harm human health, so their ingredients should be disclosed under section 904(a)(1) requirements.

Many of these components are excluded from reporting requirements under the FDA's April 2018 guidance.

FDA offers no reasonable basis in the April 2018 guidance for excluding products that were explicitly considered in the Deeming Rule and listed as examples of covered components and parts because they are reasonably expected to alter or affect the tobacco product's performance, composition, constituents, or characteristics" from the April 2018 guidance.

As explained above, ***FDA should require ingredient and materials disclosure for any part of a tobacco product that comes into contact with the portions of the product that are consumed during normal use.*** FDA should *not* wait until manufacturers submit PMTAs to possibly discover ingredients with negative health impacts; rather, it should restore the ingredients disclosure compliance policy originally stated in its January 2017 revised guidance and cover all components and parts of tobacco products that are known to or reasonably expected to alter the product's performance, composition, constituents, or characteristics and/or that come into contact with portions of the product that are consumed during normal use.

Moreover, the distinction FDA made for components or parts that are not "burned, aerosolized or ingested" may have the effect (whether or not intended) of excluding from the listing requirements many components or parts of new heated tobacco products like IQOS, which has submitted PMTA and MRTP applications***. At the very least, FDA should change the word "burned" used in its April 2018 guidance to "heated" so the components and parts of heated tobacco products would be subject to the ingredients disclosure policy. It should also remove all components listed in the Deeming Rule from the list of exemptions in the guidance.*** This is especially important because these products are so new that extensive scientific evidence about the health effects of the ingredients and materials in the products, including their components and parts, is not yet available.

4. Conclusion

- FDA's new revised compliance policy for the ingredients submission requirements does not protect the public health as required by law. In limiting its coverage only to components and parts "that are burned, aerosolized or ingested during tobacco product use," it fails to require disclosure of ingredients in many of the components and parts of tobacco products that may

affect the toxicity of those products. Therefore, ***FDA should require ingredient and materials disclosure for any part of a tobacco product that comes into contact with the portions of the product that are consumed during normal use.***

- Of particular concern, burning charcoal briquettes (which are components of hookah that FDA's new compliance policy would excuse from ingredients listing requirements) are a unique source of toxicant emissions specific to hookah smoking. ***Therefore, it is vitally important for FDA to require manufacturers to submit the listing of ingredients in hookah charcoal.***

- In addition to the direct health implications of many of these ingredients, FDA should take into account the potentially significant environmental health consequences of these products and their components and parts.

- FDA's new compliance policy is not in keeping with the definitions of "tobacco products," "components," or "parts" that are clearly spelled out in the law, and contradicts FDA's own clear analysis of these terms found in the Deeming Rule and earlier versions of the guidance.