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

RE: Docket No. FDA-2012-D-0049

To Whom It May Concern:

The American Lung Association has submitted comprehensive comments about the Food and Drug Administration's (FDA) Draft Guidance for Industry on Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under section 904(a)(3) of the Federal Food, Drug, and Cosmetic ACT (HPHC) in conjunction with other public health partners. These comments are submitted as a supplement to those comments, and represent the views of the American Lung Association.

Given the tobacco industry's infamous and well-documented history of lies and deception regarding the physical components of its products, including the extremely addictive and lethal nature of these products when used as directed, the American Lung Association urges FDA to ensure that any disclosures regarding harmful and potentially harmful constituents must not make direct or implied claims about the health impact of the tobacco products based on the presence or absence of specific ingredients or constituents. FDA must further ensure that any public disclosures of ingredient lists or any statement made about such disclosures cannot and do not create or lead to misperceptions about the relative risk of different brands or products. Therefore, the American Lung Association emphatically reiterates its call for FDA to conduct surveys that demonstrate how consumers actually perceive and digest information to guarantee that consumers are not misled by published lists of ingredients. This HPHC information must be made available to the public in a manner that does not confuse or mislead consumers about the relative safety or health impact of products based on the presence or absence of ingredients found on any published HPHC list.

Additionally, the American Lung Association urges FDA to conduct follow-up studies on consumer perception of information to confirm that the public has not been confused or misled. These studies should analyze, among other things, the relative costs and benefits of the disclosure of HPHCs. Also, the FDA's studies should look in particular at the impact of eliminating

73 HPHCs from the initial list of HPHCs, and whether this exclusion inadvertently implies that these products are more safe or less harmful than the ingredients included on the newer HPHC list that is the subject of this Guidance.

The Surgeon General recently reported that every day more than 1,200 Americans die due to smoking, and for each of those deaths, at least two new people become regular smokers.¹ The onus is on FDA to attack this epidemic of tobacco use by stemming the tide of misleading, deceptive, and confusing information about the health impacts of tobacco products.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul G. Billings". The signature is fluid and cursive, with the first name "Paul" being the most prominent.

Paul G. Billings
Vice President, National Policy and Advocacy

¹ HHS, *Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012
<http://www.cdc.gov/Features/YouthTobaccoUse/>