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December 22, 2011

Division of Dockets Management (HFA305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2011-N-0467

To Whom It May Concern:

The American Lung Association has submitted comprehensive comments about the Food and Drug Administration's (FDA) Draft Guidance on Applications for Premarket Review of New Tobacco Products (Draft Guidance) in conjunction with other public health partners.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.

The Family Smoking Prevention and Tobacco Control Act (FSPTCA) grants the FDA broad authority to regulate the manufacturing, distribution, and marketing of tobacco products. Recognizing that when used as intended tobacco products are deadly, the statute created rigorous standards that new products must meet, and unambiguously placed the burden on the tobacco industry to prove that these standards have been met before new products are introduced.

In particular, the standard provides that a new product may not be introduced unless the FDA determines that the introduction of the new product is "appropriate for the protection of the public health [considering] the risks and benefits to population as a whole," and considering the increased or decreased likelihood that non-users will start using such products and the increased or decreased likelihood that existing users will quit. The statute allows FDA to determine what specific evidence to consider, including product components, smoke constituents a consumer is exposed to, impact of such exposure on the consumer, and evidence relevant to consumer perception and consumer behavior, including packaging, ease and attractiveness of use, and other design changes. Additionally, FDA asks for information about the "attractiveness" of new tobacco products. The standard requires the tobacco manufacturer-applicant to demonstrate to FDA that the proposed new product would not make it more likely that non-tobacco users, especially youth, will begin to use,

or more likely that current tobacco users will increase their use or that fewer will quit. The statute clearly provides that the burden is on the tobacco industry to provide evidence-based data.

Unfortunately, given the tobacco industry's infamous history of lies and deception regarding not only the physical components of its products, but also the intangible "attractiveness" of its deadly products, especially to youth, it is unreasonable and inappropriate for FDA to rely on representations made by the tobacco industry about the public health impacts of their products in their premarket applications for new tobacco products. Indeed, in its recently published report on Scientific Standards for Studies on Modified Risk Tobacco Products (MRTP), the Institute of Medicine (IOM) found that "[i]t has been established in public records and as a matter of law that the tobacco industry has engaged in illegal and improper practices, including the destruction and manipulation of scientific data," and that as a result, "the tobacco industry is profoundly isolated from the mainstream scientific community," and consequently lacks "the expertise and the resources necessary to produce high-quality science across the range of disciplines" to support a premarket application for MRTPs. Recognizing FDA's need to have *credible and reliable* evidence on which to evaluate tobacco products about the effects of tobacco products on the public's health, the IOM made the following recommendation:

> Recommendation 10: MRTP sponsors should consider use of independent third parties to undertake one or more key functions, including the design and conduct of research, the oversight of specific studies, and the distribution of sponsor funds for research. Such independent third parties should be approved by the FDA in advance of the research. [1]

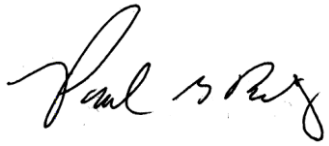
The IOM's report underscores the necessity for FDA to base its decisions regarding new product applications on credible and reliable evidence, and emphasizes the reality that they cannot and should not count on the tobacco industry to provide such high quality evidence. While IOM's report concerned MRTP applications, its arguments are equally valid here. The American Lung Association urges FDA to require that independent third parties, previously approved by FDA, must conduct and submit scientific studies to support applications for premarket review of new tobacco products submitted by tobacco manufacturers. This independent research and expertise is essential to produce high-quality, credible, and reliable scientific reports about the effects of tobacco products on the public health upon which FDA can rely to make its decisions as required by the FSPTCA.

It is clear that in order for FDA to carry out its mandated duty to protect public health by regulating the introduction of new tobacco products by an industry known for its continuous efforts to mislead consumers and authorities, it must require trustworthy independent parties that have been pre-approved by the FDA to conduct and verify research and provide credible

[1] Institute of Medicine. *Scientific Standards for Studies on Modified Risk Tobacco Products*, page 15.

evidence regarding the claims made by tobacco manufacturers regarding proposed new products.

Sincerely,



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