November 13, 2009

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

RE: Docket Number FDA-2009-D-0524

To Whom It May Concern:

We commend the Food and Drug Administration (FDA) for issuing in such timely fashion its draft guidance document for listing ingredients in tobacco products. This is an important step to meet the deadline established by law for setting up a system to require tobacco companies to register and submit information to the FDA pursuant to sections 904 and 905 of the Family Smoking Prevention and Tobacco Control Act. The information required of the companies will be critical to FDA's mandate to inform consumers of the hazardous substances in tobacco products, as well as in its efforts to reduce tobacco use and its harms.

We would like to make several specific recommendations:

1) Given the volume of information that FDA will receive, the scientific complexity of the information, and the fact that information will be submitted for so many different brands, a very high priority should be using and requiring registrants to use an electronic system that will allow FDA not only to receive the information, but to access it and use it effectively. FDA has encouraged manufacturers to use the electronic eSubmitter application, but does not require it. We urge the FDA to require that all information be submitted electronically according to a detailed system established by the FDA and that the FDA notify all parties that it reserves the right to modify the electronic system for filing and receipt of this information if necessary to enable FDA to access and use it effectively.

2) Given the fact that no federal agency has had access to the breadth of information covered by sections 904 and 905 previously, the Guidance should say explicitly that FDA reserves the right to ask for information in a different form and format, as well as to ask for different information once it has had the opportunity to review the information received and to make adjustments in the future as it deems appropriate. Clearly, the early data submissions will be instructive in terms of what else the FDA will want to ask for and how. Therefore, the FDA should not lock itself into a formula that inhibits its ability to analyze and use the data or that allows the tobacco industry to provide the data in a way to make it more difficult for FDA to carry out its tasks.

3) While the Proposed Guidance deals only with the Listing of Ingredients, Section 904(b) authorizes the Secretary to request certain information related to documents and research findings conducted before the date of enactment, and we urge the FDA to place a priority on

exercising the authority under this section as well. The clear goal of this section was to give the FDA access to vitally important data and research it will need to carry out its functions under the Act, but also recognizes the fact that the quantity of documents potentially covered is enormous. The section 904(b) authority is likely to be extremely important to enable FDA to set priorities with regard to product standards and evaluate the role of various ingredients and constituents and to more fully and accurately assess the impact of potential rules regarding the content of tobacco products. It will also be important to aid the work, including the reports and recommendations, of the Tobacco Products Scientific Advisory Committee.

For example, there have been studies indicating that changes in nitrosamine levels over the years have potentially increased the risk of lung cancer among smokers. Other studies and industry documents have demonstrated how the use of ammonia has increased the addictive power of nicotine in tobacco products. Still others have identified the role of menthol in youth initiation and difficulties in cessation. Research has also revealed other ways the tobacco companies are known or are suspected to have made changes to their products that have resulted in more people using and dying from tobacco products.

We recommend that the FDA quickly establish a system for making requests for information under Section 904(b). There is likely much research that is in the possession of the tobacco industry related to the impact of ammonia technology, nitrosamines, menthol, and a myriad of other ingredients or constituents. The information requests should be based upon an assessment of which areas offer the greatest possibility for reducing the death toll from tobacco, as well as which areas are necessary for the FDA to most efficiently carry out its legislative mandate, including the Congressional mandate for the Scientific Advisory Committee to make it a priority to focus on menthol.

4) Again, while this Guidance focuses on Section 904(a), we urge the FDA to make it a priority to exercise the authority granted to it under Section 904(b)(3) because the impact of tobacco products is directly affected by how these products are marketed. Section 904(b)(3) authorizes FDA to obtain information about marketing and marketing research. FDA should establish priorities for obtaining this information based on those marketing practices that continue and based upon its assessment about which marketing practices may be having the greatest impact on public health.

5) In revising this guidance we urge the FDA to pay close attention to the scientific advice that is contained in the comments by a number of public health leaders, such as David Burns M.D., Dorothy Hatsukami, Ph.D. and Stephen Hecht, Ph.D. and others, who have previously been involved in the editing of major reports of the Surgeon General and National Cancer Institute on tobacco. They are extremely knowledgeable.

6) The FDA is not the first governmental agency in the world to seek to obtain information concerning tobacco ingredients. Canada and the European Union both have experience. FDA should look closely at the form, format and breadth of information required by Canada and the EU to be certain that the FDA learns from the experience of these governmental entities.

7) The tobacco industry is notorious for its prior success in undermining public health efforts regarding its products. Therefore, it is critical that clear definitions for sub-categories of information be specified, e.g. filler, adhesive, paper, filter overwrap, inks, etcetera, and that it be clear that detailed information must be provided for the multiple sub-categories of components to a final tobacco product. We also recommend that the manufacturers be required to submit information, in addition to any amounts of any ingredient added, the quantity of each such ingredient that is in the final product at the conclusion of the manufacturing process and that all reporting be required in the unit of use form, i.e. by each individual cigarette, pouch of smokeless tobacco, and by standardized amounts for products sold in packages where the consumer self-selects the amount used in a single dose.

8) Tobacco is one of the ingredients in the products covered by the Act. The Guidance should be much more precise in how the tobacco used in individual products is reported. Many tobacco products are the result of the mixture of more than one type of tobacco or tobacco from different parts of the tobacco leaf. How tobacco is blended impacts the presence and quantity of different toxins, carcinogens and addictive substances. Therefore, manufacturers should be required to specify the precise blend of tobacco in each unit of each sub-brand, the different types of tobacco leaf found in the product by quantity found in each cigarette, any genetic or transgenic modifications to the tobacco and any quality or content defining parameters associated with the raw tobacco materials used in the product.

In addition, tobacco companies should be required to specify whether the product contains "reconstituted tobacco," and if so, the specifications for the mixture and any range of variability permitted for the mixture.

Again, we commend the FDA for its thorough and timely action and look forward to the final Guidance document.

Sincerely,

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