

**LAUTERBACH & ASSOCIATES, LLC**  
**CONSULTING SCIENTISTS**  
**CHEMISTRY • TOBACCO SCIENCE • TOXICOLOGY**

December 28, 2009

SUBMITTED VIA WWW.REGULATIONS.GOV

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

RE: REGULATION OF TOBACCO PRODUCTS; REQUEST FOR COMMENTS, DOCKET NO.  
FDA-2009-N-0294: **WHERE IS THE SCIENCE AT THE CENTER FOR TOBACCO  
PRODUCTS?**

Dear Sir or Madam:

Lauterbach & Associates, LLC, ("L&ALLC") specializes in providing advice on scientific and regulatory matters to the tobacco industry and its suppliers. L&ALLC is pleased to comment on the regulation of tobacco products as requested in the subject docket. L&ALLC is particularly well qualified to comment on the regulation of tobacco products, including cigarettes and other smoking articles, pipe and "roll-your-own" blends, and smokeless tobacco products ("STP").

L&ALLC's Principal in Chemistry and Toxicology, Dr. John H. Lauterbach, is an internationally recognized expert in the chemistry and toxicology of tobacco, tobacco products, and tobacco smoke. Prior to founding L&ALLC in October 2004, Dr. Lauterbach was employed in leadership positions at Brown and Williamson Tobacco Corporation (B&W). From 1996 to 2004, he was Principal Scientist in B&W's Scientific & Regulatory Affairs ("S&RA") group, where he led the technical work on the most difficult ingredient evaluations. He is also an expert on the formation and analysis of reaction products that are formed during tobacco processing. Prior to his position in the S&RA group, Dr. Lauterbach was Director, Research Services, and had responsibility for both the routine and detailed analyses of tobacco products and tobacco smoke. Dr. Lauterbach is a Diplomate of the American Board of Toxicology and is both a Chartered Scientist and a Chartered Chemist.

In Dr. Deyton's comments (Regulating Tobacco: Q&A with Lawrence Deyton, M.S.P.H., M.D.) that were published in the September 2009 issue of FDA Consumer Health Information, he stated, "Science will guide all of our actions to reduce the public health toll from tobacco products in the United States. For example, science will help us understand tobacco and its ingredients and constituents, tobacco addiction, tobacco marketing and labeling, and childhood tobacco use." However, there appears to be a major gap between what Dr. Deyton has said and what is happening in the Center for Tobacco Products ("Center" or "CTP"). When the Center published its Draft Guidance for Industry on Listing of Ingredients in Tobacco Products (Docket FDA-2009-D-0524), we were very surprised by the lack of science in that document and the apparent lack of scientific thought that was put into it. In that draft guidance document, your agency asked for the results of very detailed analyses of tobacco products that were beyond the training and experience of most analytical scientists skilled in testing tobacco products. Those analyses are not available through the commercial testing laboratories that have the equipment, personnel, and expertise to analyze tobacco products. More importantly, there are no standard

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methods (e.g., ISO, CORESTA, Health Canada) for the FDA mandated analytes and matrices. Clearly, the content of Draft Guidance document did not represent good science. Thus, we took the time to prepare and send in detailed comments. You can also find them in the docket folder at FDA-2009-D-0524-0011.1.

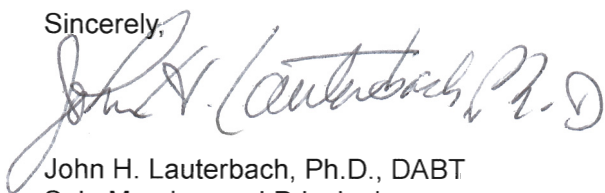
Since we have more expertise than most scientists do have in the areas covered by the aforementioned Draft Guidance, we had some hope that CTP scientists would consider our recommendations carefully and contact us if they had questions. We had hoped that good science would prevail when in the final Guidance for Industry was published on November 27. Unfortunately, good science did not prevail. The bad science in the Draft Guidance was not removed. Moreover, there was no recognition of the time it would take to develop the methodology to provide the requested information let alone the time and costs for obtaining and qualifying the scientific instrumentation, training staff, and validating the analytical systems at each laboratory that would be performing the analyses. Furthermore, and most importantly, the information CTP would get from these difficult and detailed analyses likely is of little value dealing with issues of attractiveness of tobacco products and their chronic and acute toxicities. Such bad science does not enhance the credibility of the Center for Tobacco Products.

From the dealings my company has had with CTP, as well as from reports we have heard from others in the tobacco industry, it appears that the Center has an extreme shortage of knowledge and practical experience on the science and technology associated with the manufacture and testing (physical, chemical, hedonic, and toxicological) of tobacco products. In addition, we have offered to help your Small Business Assistance group provide advice to the smaller tobacco product manufacturers and our offers have been refused. I am sure you have heard this from others. Furthermore, unlike pharmaceuticals and foods, there is not a large academic community that can provide the needed expertise. You are not likely to find academic faculty who know how to identify and quantitate reaction products formed during burley redrying, or how to spot the reaction products found in certain flavored styles of STP, or how to identify trace level contaminants that would make a tobacco product adulterated, or how to spot data quality problems on a submission for a modified risk tobacco product.

My company, Lauterbach & Associates, LLC, can provide you with the expertise to answer your immediate technical questions and train your scientific and regulatory personnel on the key aspects of tobacco science, chemistry, and toxicology. Our fees are reasonable, and we can move quickly to get you the assistance you need now.

Please let us know if you would like more information.

Sincerely,



John H. Lauterbach, Ph.D., DABT  
Sole Member and Principal  
Chemistry and Toxicology