

**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: **TEST METHODS FOR TOBACCO PRODUCTS AND TOBACCO  
SMOKE**

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"), and the test methods used to characterize the chemical, physical, and toxicological properties of those substances. L&ALLC is a member of the US Technical Advisory Group ("USTAG") to International Organization for Standardization (ISO) Technical Committee 126 on Tobacco Products ("ISO TC126") and is a member of CORESTA (Cooperation Centre for Scientific Research Relative to Tobacco). Both CORESTA and ISO TC126 are involved in developing standards for the testing of tobacco products and tobacco smoke.

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. 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 and the development of test methods for 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.

Several parts of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA") such as Section 915 require the testing of tobacco products and tobacco smoke (for cigarettes and other smoking products). No test methods were specified. In addition, in its Guidance for Industry – Listing of Ingredients in Tobacco Products, November 2009, the Center for Tobacco Products ("CTP") recommended that several chemical tests be run on tobacco products to provide data needed for reporting of ingredients. However, no test methods were specified. Even though some of the analyses recommended (e.g., tests to determine identity and concentrations of reaction products) would require complex and difficult analyses, the CTP did not recommend the analytical methods to conduct such tests. Even reporting of simple information such as the

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nicotine content of tobacco products has had to be postponed for supposedly lack of suitable test methods. This situation is different from other jurisdictions (for example, European Union, Brazil, Canada) that specify use of the ISO standards for testing tobacco products or standards developed by governmental agencies such as Health Canada.

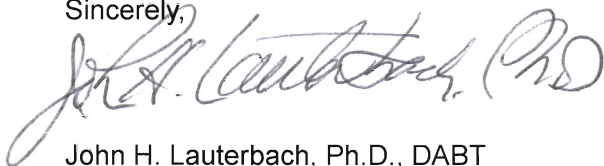
The development of new test methods to meet the reporting requirements of the FSPTCA would likely involve considerable cost and time for the CTP to develop its own test methods. It can take several years for development and full validation of a tobacco related test method (including interlaboratory studies of method precision and bias). Such delays not only would be counter to the objectives of the FSPTCA, but would also make planning difficult for those who provide commercial testing of tobacco products and the smaller tobacco product manufacturers (“STPM”) that will need to rely on such laboratories to provide the data needed to meet the reporting requirements of the FSPTCA. While Section 915 provides some relief to the STPM in the event there is insufficient testing capacity, there is likely a better way to reduce the costs and uncertainty associated with the new methods developed by the CTP. The better way would be for the CTP to adopt the Health Canada test methods for testing the tobaccos in cigarettes and other smoking products as well as the smoke from such products. These test methods have been used for almost ten years and the major commercial tobacco testing laboratories are familiar with them. The full method details are available without charge on the Internet at <http://www.hc-sc.gc.ca/hc-ps/tobac-tabac/legislation/reg/indust/method/index-eng.php>.

The Health Canada test methods offer several advantages. First, they were developed by a governmental agency, not the tobacco industry or organizations such as CORESTA and ISO TC126 that have tobacco industry participation. Second, the Health Canada Intensive (“HCI”) smoking protocol accounts for consumer smoking behaviors that result in higher smoke intake than would be shown with the now-obsolete FTC method. Third, the test methods have been developed, validated, and there is a sizeable collection of data in the public domain on cigarettes and other smoking products of spanning the range of commercial products. Fourth, by adopting the Health Canada methods, the CTP can devote resources to other test methods that may need to be developed to meet the requirements of the FSPTCA. These advantages far outweigh any advantages that the CTP could accrue by developing its own methods for the same analytes.

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 test methods for tobacco and tobacco smoke. 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