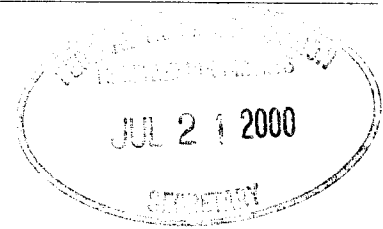




**Star**

Scientific, Inc.

July 21, 2000



Secretary  
Federal Trade Commission  
Room H-159  
600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20580

RE: Comments Concerning Implementing the Comprehensive Smokeless Tobacco Health Education Act, 16 CFR Part 307

Dear Madam/Gentlemen:

Star Scientific, Inc. ("Star Scientific" or "Star") appreciates the opportunity to provide comments on the Federal Trade Commission's ("FTC") review of regulations implementing the Comprehensive Smokeless Tobacco Health Education Act of 1986. Since certain of the suggested areas of response are not within our area of competence, we will address only those areas of focus where we believe we may be in a position to be of some assistance to the FTC staff.

Star Scientific, although in the tobacco business, is a company with a very different mission and set of goals and objectives when compared to other conventional tobacco companies, including those which manufacture smokeless tobacco products. As our attached **Policy Statement** indicates, the issue of public health is a major consideration of our business philosophy, as well as our business practices. One of our primary corporate missions is the reduction of the range of serious health hazards associated with the use of conventional tobacco. We believe that in order to advance significant public health interests, the manufacture, sale, distribution, labeling and marketing of all tobacco products should be regulated by the Federal Food and Drug Administration ("FDA"). However, until such regulatory authority is vested in the FDA, we appreciate the vital role that the FTC continues to play in ensuring that the public is adequately informed about the range of serious health risks associated with smoked tobacco use, as well as the use of conventional smokeless tobacco products.

As the FTC indicated in its *Federal Register* notice, the primary purpose of the 1986 Act is **to educate the public about the adverse health effects of smokeless tobacco use**. As noted below, we regard the warning labels as an essential component of what must be a comprehensive public education effort that should also include:



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- Accurate and truthful information about the product
- Prohibiting misleading and deceptive advertising and promotion practices
- Establishing a regulatory system that is able to fairly and effectively deal with changes in the market place

As part of its request for comments, the FTC raised several specific questions concerning the labeling of smokeless tobacco products. Star will address a number of these specific issues but believes that there are broader issues for the FTC to consider as it contemplates revisions and changes to the regulations. Much has changed since the law was enacted, and we believe there are opportunities and options that need to be considered in order to adequately protect and educate the public from the risks of all tobacco products. Some of these may require that the FTC approach Congress for changes in the law.

Any consideration of these dramatic changes must necessarily focus upon the most potent and abundant carcinogenic agents in conventionally cured tobacco leaf, i.e., the tobacco specific nitrosamines ("TSNAs").

At the time of the enactment of the original implementing legislation (i.e., the Comprehensive Smokeless Tobacco Health Education Act of 1986) relating to smokeless tobacco, TSNAs were well known in the scientific literature, yet no national or international tobacco company acknowledged the sinister role which these cancer-causing agents play in the mortality and morbidity associated with long-term use of smokeless tobacco. That situation has changed appreciably today, as a direct result of Star's 5 year commitment to development efforts aimed at reducing the toxicity of tobacco to the maximum extent allowable, given available technologies. Star has been acknowledged as the world leader in developing a commercially viable technology (patents issued and patents pending) to preclude the formation of TSNAs during the curing process, thereby reducing to very low or virtually undetectable levels TSNAs in both flue-cured and burley tobacco.

Although most other conventional companies have belatedly followed Star's leadership, only one major company, Brown & Williamson Tobacco Corporation ("B&W"), has made a major commitment to embrace Star's technology which consistently produces the lowest possible levels of these carcinogenic compounds in the tobacco leaf and in second hand smoke. As Sharon Boyse, B.A., Ph.D., Director of Scientific Issues, Brown & Williamson Tobacco Corporation, has stated:



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After looking at various ways to reduce the tobacco specific nitrosamines (TSNAs), B&W has concluded that the StarCure™ process is by far the most effective in achieving the lowest possible toxic levels. B&W plans to continue to expand its support of the StarCure™ process.

Star is obviously pleased that other tobacco companies have recognized the verity of Star's proprietary process, which has changed the way in which tobacco has been cured for the past 100 years

Star believes that it is appropriate and necessary for smokeless tobacco products to carry effective rotating warning labels. There are numerous examples of tobacco product warning labels throughout the world that can be used as models for U.S. labeled smokeless tobacco products, and they merit close examination. However, there are two considerations that should also be factored into the final decisions about exactly what these labels contain.

First, the technology for producing smokeless products has changed, and it is now possible to produce smokeless products that will represent substantially reduced health hazards.

As referenced above, TSNAs are considered to be the most significant cause of disease in smokeless tobacco products. Star, and arguably others that have followed Star, now have technologies that will allow TSNAs to be significantly reduced in smokeless products. The FTC should consider ways of providing the public with information about the levels of toxins in smokeless tobacco, including, but not limited to, nicotine and TSNAs. This could be done either by a separate label on the pack and in the advertisement or through the inclusion of "package inserts" and information made available through the Internet (as Star has done on its new scientifically-oriented website -- [www.starscientific.com](http://www.starscientific.com)). We believe that truthful, accurate, and balanced information about the products must become the standard in the industry. In light of these technological changes, not all smokeless tobacco products will be equal in terms of potential health risks. As new products are introduced, there must be a regulatory system in place that not only is able to prescribe the proper and accurate labeling requirements but also ensure how the advertising and marketing of these products will take place.

Also, there is evidence that microbial activity in smokeless tobacco can lead to an increase in the levels of tobacco specific nitrosamines in smokeless tobacco products during storage prior to sale. The extent to which this can occur depends on the tobacco



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itself, its moisture content, temperature storage, as well as its date of manufacture. We believe that, as a potential public health issue, products should be labeled as to the date of manufacture, and there should be specific instructions provided retailers and possibly consumers that certain products used after a certain date, if not properly stored, may have increased levels of nitrosamines.

The second consideration deals more with the overall problem of the adverse health effects of the full range of tobacco products. There is a general consensus that the most toxic form of tobacco consumption involves the inhalation of tobacco smoke deep into the lungs. Compared to the smoking of cigarettes, the use of smokeless products, even those conventional smokeless tobacco products with current high levels of nitrosamines, produce far less hazard to the health of the users and virtually none to those in the users' environment. To the extent that cigarette smokers elect to use smokeless products instead of cigarettes, there will be a general beneficial effect on the public health. See recent data from Sweden.<sup>1/</sup> It is probably not good public health policy to discourage the use of the least hazardous tobacco products with the same vigor used to discourage the use of the most toxic tobacco products. Many of these issues need to be sorted out by qualified scientists and the medical community (in both the public and private sectors).

Although we have raised issues that go beyond the scope of revisions in the labeling of smokeless tobacco products and enforcement of those regulations, we believe that the time has come for federal regulatory agencies and the Congress to take a more comprehensive approach to tobacco product regulation and establish a fair and equitable system that sets the appropriate standards for **the manufacture, labeling, sale and distribution, and marketing of all tobacco products.**

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<sup>1/</sup> Nilsson R (1998): A qualitative and quantitative risk assessment of snuff dipping. *Regulatory Toxicol Pharmacol*, 28:1-16; Lewin F, et al. (1998): Smoking tobacco, oral snuff, and alcohol in the etiology of squamous cell carcinoma of the head and neck. A population based case-referent study in Sweden. *Cancer*, 92:1367-1375; Schildt E-B, et al. (1998): Oral snuff, smoking habits, and alcohol consumption in relation to oral cancer in a Swedish case-control study. *Int J Cancer*, 77:341-346.



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If the Commission or staff would be assisted by our responding to further questions, we would be pleased to be responsive to any relevant queries regarding our submission.

Respectfully submitted,

A handwritten signature in black ink, reading "Paul L. Perito". The signature is fluid and cursive, with a large initial "P" and "L".

Paul L. Perito, Esquire  
President and Chief Operating  
Officer <sup>2/</sup>

Attachment  
PLP:mek  
WDC/152905.1

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<sup>2/</sup> Temporary Executive Office Address: c/o Paul, Hastings, Janofsky & Walker  
LLP, 1299 Pennsylvania Avenue, N.W., Tenth Floor, Washington, D.C. 20004.  
Telephone: 202-508-9500. Facsimile: 202-508-9700 or 9766.

801 Liberty Way • Chester, Virginia 23836  
Phone (804) 530-0535 • FAX (804) 530-8474



# Star

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## POLICY STATEMENT FOR STAR SCIENTIFIC, INC.

### *Responsible Standards For Changing Certain Prevalent Views in the Tobacco Industry*

- STAR SCIENTIFIC accepts and supports *effective* measures at the national, state and local levels to ensure that tobacco products are not distributed, sold, or marketed to children and adolescents.
- STAR SCIENTIFIC accepts the findings and conclusions of the Surgeon General of the United States, as well as the informed public health community, that conventionally cured tobacco is a major factor in disease and addiction and that those who use tobacco products who wish to quit should be given incentives and opportunities to do so.
- STAR SCIENTIFIC acknowledges that the use of tobacco products generally poses health hazards and that no known tobacco product or process, even the process that Star has developed, while virtually eliminating nitrosamines, eliminates all health hazards associated with the smoking of tobacco.
- STAR SCIENTIFIC supports having the Food and Drug Administration (FDA) as the lead regulatory agency charged with overseeing the implementation of fair and meaningful regulations over the manufacture, sale, distribution, labeling and marketing of all tobacco-containing products.
- STAR SCIENTIFIC supports increased biomedical and allied research by the private sector, as well as such federal agencies as the FDA, NIH, CDC, and the USDA, that will continue to identify and understand the complexities of what causes the diseases associated with tobacco use and work to find ways of reducing and/or eliminating these causes, and setting standards and "bench marks" for the development of reduced risk and less hazardous tobacco products.
- STAR SCIENTIFIC believes that it has a corporate responsibility to continue to expand research and development efforts to manufacture tobacco products that are as safe as is technologically possible to address the serious public health problems associated with tobacco use, and to respond to the needs of adult tobacco users who continue to consume tobacco products notwithstanding the broad range of health risks associated with using such products.
- STAR SCIENTIFIC believes that adults who choose to smoke and/or make an adult choice regarding the use of any tobacco products should be fully and completely informed about the dangers of the tobacco products they choose to use, including specific information regarding ingredients and constituents of tobacco and tobacco smoke and the levels of such toxic constituent elements in tobacco and tobacco smoke. This should include any scientifically established information that indicates that a product may or will reduce certain exposure to major toxic elements associated with tobacco use.
- STAR SCIENTIFIC is committed to working with the public health community, the FDA, and other federal regulatory agencies in seeking to prevent the use of tobacco products by children and adolescents and in the scientific development of products that have the potential for lessening or even eliminating the incidence of disease, death and addiction associated with tobacco use.
- STAR SCIENTIFIC believes that the time has come for health groups, researchers, scientists, policy makers, senior government officials, tobacco farmers and responsible tobacco companies to sit down and talk about the future of tobacco and the tobacco industry, including an articulation of reasonable parameters under which new products that *will reduce exposure to certain toxic constituents in tobacco and tobacco smoke can be developed, evaluated and marketed.*

[www.starscientific.com](http://www.starscientific.com)

• 801 Liberty Way • Chester, Virginia 23836 •  
Phone (804) 530-0535 • FAX (804) 530-8474 •