

**New Standards for the Labeling and Marketing
of Tobacco Products
Background Statement by Star Scientific, Inc.
Concerning the Initial Test Marketing of Advance
(in Virginia and Kentucky)**

Star Scientific, Inc. ("Star") remains committed to supporting the regulation of all tobacco-containing products by the FDA. We will continue to advocate that goal, as well as our support for the Framework Convention On Tobacco Control ("FCTC"). Star is also committed to supporting **comprehensive** tobacco control programs and activities both in the US and abroad that focus on the goal of reducing health hazards associated with the long-term use of tobacco. Our relatively young public company is premised upon the concept that in a world where 1.2 billion people take smoke deeply into their lungs each day, and where many of them will die prematurely as a result of smoking-related illnesses, there is an urgent need to manufacture tobacco products in the least hazardous fashion possible, given available technologies. Star is a technology-oriented tobacco company with a health-related corporate mission. We believe Star has developed one of those technologies (StarCure™) and has an obligation to make potentially less hazardous products available to adult tobacco consumers. Star's focus will be on providing adult consumers with detailed and extensive information about smoking constituents and related health/risk issues under the banner "Know what you smoke." Although we have stated repeatedly that there is no such thing as a safe cigarette, and we do not believe that a safe cigarette product will ever be manufactured in the future, we nonetheless believe a "prohibition model" to be counterproductive. "Cessation" ought to be the first consideration of any long-term smoker. Obviously, never starting ought to be the first consideration of someone who is contemplating using tobacco products. Yet, since we recognize that it is highly unlikely for a range of reasons, including nicotine addiction, that a significant portion of the 1.2 billion people who smoke each day will quit in the near future, there is a compelling need for tobacco product modification, based upon good science, coupled with appropriate and responsible changes in the way in which tobacco products are labeled and marketed. In short, there must be a rational and comprehensive tobacco control strategy, both in the U.S. and internationally.

We hope that the announcement of our initial limited test marketing (in Virginia and Kentucky) of Advance, the first conventionally-manufactured cigarette that delivers significantly less tobacco specific nitrosamines ("TSNA's"), and which has an activated charcoal/acetate filter which reduces several additional toxic constituents, will prod the traditional tobacco manufacturers to also consider producing less toxic products and appropriately labeling their products more fully. We need to provide adult tobacco consumers with detailed and specific disclosures about the toxic constituents of tobacco smoke, as well as enhanced health warnings.

We believe we have been a catalyst for change in the tobacco processing industry, *i.e.*, through the use of the StarCure™ tobacco curing method. Hopefully, we can replicate that effort in the tobacco product manufacturing industry. We are attempting to demonstrate the commercial viability of producing tobacco products (both smoked and smokeless) that hold the promise of being designated, at a subsequent stage, when there is both government regulation and adequate independent science, as "reduced

risk" tobacco products. We now must confront the reality that there is not adequate comprehensive tobacco regulation. Accordingly, we are doing our best to make available tobacco products that deliver significantly less toxins in an environment where we have no adequate government regulation or legislative guidelines regarding appropriate levels of toxicity, disclosure and appropriate restraints on marketing and advertising.

We recognize what we are doing is not perfect. We will continue to remain open to suggestions from the public health and scientific communities, as well as government regulators, on how we can improve upon what we are doing. As we move forward in this process, we will continue to promote rational comprehensive government regulation, while at the same time openly sharing our data and information with the responsible segment of the scientific and public health communities, as well as with governmental bodies such as the FTC, FDA, CDC and Surgeon General's Office. We are hopeful that what we are doing will stimulate serious and meaningful dialogue about how tobacco-containing products should be manufactured, labeled, marketed and advertised in the coming years. In short, we are in vital need of a comprehensive regulatory scheme and structure housed in the lead health agency, *i.e.*, the Food and Drug Administration.

The introduction of Advance, a prototype low TSNA cigarette, is intended to incorporate a number of goals and objectives. Several of these goals and objectives have been recommended by responsible members of the public health and scientific communities, most recently in the 29th Surgeon General's Report relating to smoking and health, which the Surgeon General promulgated a few weeks ago (Surgeon General's Report, **Reducing Tobacco Use--A Report of the Surgeon General.**) We view our efforts not as a conventional "rollout" of a new tobacco product but rather as a "rollout" of a new way of reducing toxins in tobacco and labeling products in such a way as to provide increased "informed consent" for consumers. Concomitantly, no such effort should be conducted without heeding the admonitions of the Surgeon General, as well as other members of the public health and scientific communities, who have recommended enhanced health warnings and broad disclosure of the toxic constituencies of smoke, among other things. We, unlike other companies, have acted before there is a Congressional statutory mandate or federal agency regulation. Accordingly, there is no rational template against which we can measure Star's initial limited test market of Advance, so we must be guided by the input and counsel of the scientific and public health professionals who have assisted us during the development and testing of Advance. In a parallel fashion, we believe that, as part of the "broad labeling" of any tobacco-containing product, our product labels must include enhanced health warnings and comparative toxic constituency information. We recognize and have tried in our labeling to make clear to the public that "there is no such thing as a safe cigarette product" and that Star's new methods, that deliver reduced carcinogenic toxins in tobacco and tobacco smoke, have not yet been proven by appropriate scientific studies to show that a reduction in known toxins results in a reduction in health risks. We believe that adult tobacco consumers deserve the opportunity to make a more informed choice about what dangerous compounds they are putting into their bodies. Accordingly, our initial public efforts will include:

- Using the Advance package with enhanced health warnings, including a series of rotating package "onserts", and an enhanced health-oriented Website, as a means of providing more comprehensive, accurate, and balanced information

and warnings on a spectrum of topics and issues including: toxins, adverse health effects, the impact of low tar and nicotine products, tobacco additives and quitting.

- Using existing StarCure™ technology, as well as other recognized technologies, to reduce known toxins in smoke, other than the TSNAs, which have been identified as causing a range of diseases associated with long-term tobacco use. We recognize that reducing or eliminating any one toxin in cigarette smoke has not yet been shown to establish a direct diminution of health risks.
- Beginning a process of toxin disclosures (both as part of our "onserts" and on our Website) that provide specific and comparative analysis of those toxins with other leading comparable brands.
- Using advertising (no traditional type of advertising will be conducted during the initial Advance test marketing phase) that does not mislead or deceive the public.
- Starting an educational effort, through the use of package "onserts", about the use of descriptors (i.e., light or ultralights) for low yield products which may be misleading to adult tobacco consumers, absent additional clarifying information.
- Calling on the FTC and the Department of Health and Human Services to take appropriate action to establish an expert panel (composed of members of the scientific, public health, regulatory and industry communities) to devise descriptors for "taste" and for the range of machine measured tar delivery in tobacco products that do not inappropriately suggest or imply that the product is less hazardous.
- Evaluating labeling and educational efforts to deal with the issue of how messages are perceived by users and nonusers and conducting pre- and post-marketing evaluations of users through focus groups.

Star understands that it is sailing into uncharted waters, but as we have stated for the past two years, we are convinced this is the right thing to do. We do not know whether these novel approaches will be accepted by adult tobacco consumers. We do not know if this is a commercially viable approach but, absent government regulation, we are compelled to share with the adult public some new options based upon "informed consent". Star believes that its efforts, which are ones that have been recommended by some of the leading members of the public health and scientific communities for a number of years, are and should be part of ongoing efforts to reduce disease and death associated with long-term tobacco use.

**SURGEON GENERAL'S WARNING: Cigarette
Smoke Contains Carbon Monoxide.**