

**IN THE FOOD AND DRUG ADMINISTRATION  
CENTER FOR TOBACCO PRODUCTS**

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Petition to ban, by regulation, sales )  
price discounting as well as marketing )  
contracts that financially penalize retailers )  
who sell tobacco products where Potential )  
Modified Risk, or Modified Risk Tobacco )  
Products are sold; issue regulatory ) Docket No. FDA-2010-P-0376-0001/CP  
requirements for min-max replenishment )  
of d-alpha Tocopherol levels in cigarettes; )  
and recognize E® brand cigarettes as a )  
Potential Modified Risk Tobacco Product. )

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**Submitted by Rousseau Research, Inc., a California Corporation (RR) and  
ETOBACCO LLC, a Delaware Corporation, (ET) collectively, the petitioner.**

**July 7, 2010**

The undersigned submits this petition under 21 CFR 5.10 and the Family Smoking Prevention and Tobacco Control Act (FSPTCA) to request the Commissioner of Food and Drug to take administrative and regulatory actions.

**A. Actions requested;**

1. To ban tobacco manufacturers, distributors and retailers of cigarettes in the United States from the practice of offering free product that induces promotional sales price discounts, of any kind, for cigarettes sold to consumers, where potential modified risk tobacco products (PMRTP) and/or modified risk tobacco products (MRTP) are sold.

2. To ban tobacco manufacturers from enforcing, and distributors and retailers from participating, in any specific agreement in marketing contracts that financially punish retailers through rebate penalties, or in any other way, penalize distributors or retailers who sell PMRTP and/or MRTP; and declare, in this case, such specific parts of those agreements shall be null and void.

3. To issue a tobacco cigarette standards regulation that requires minimum 300µg., not to exceed maximum 350µg., replenishment of d-alpha Tocopherol levels, via stabilized form, as measured in cigarette mainstream cigarette smoke condensate (MS-CSC), in micrograms per stick, or a min-max standard to be recommended by the Tobacco Products Scientific Advisory Committee.

4. Recognize E® brand cigarettes as a potential modified risk tobacco product (PMRTP) prior to the brand's application for approval as a modified risk tobacco product (MRTP).

**B. Statement of grounds;**

**1. Grounds for action on A. 1.**

It is obvious that the tobacco industry is a net harm industry. Much can be learned about this subject in Crane, Daniel A., Harmful Output in the Antitrust Domain: Lessons from the Tobacco Industry. Georgia Law Review, Vol. 39, p.321. Available at SSRN:

[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=711822](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=711822)

While this Working Paper relates to antitrust, it is very relevant to the FDA in the matter of this petition and to the mission of The Center for Tobacco Control. With its wealth of facts, the work is a “must read” for anyone attempting to understand the tobacco industry’s dilemma relating to modified risk (reduced harm). Of interest is Crane’s approach, p. 326, whereby “...Part III proposes to identify net-harm markets based on a political norm of output reduction in the industry, as exemplified in federal statutes, executive orders, agency actions and other manifestations of public policy.” In his next part IV, Crane discusses potential applications of the harm reduction model to the tobacco industry. Crane’s thesis and the information revealed, before and as well as in, his Part IV, support the need for the FDA to act favorably on petition A. 1. In addition to the above, the petitioner’s grounds for action in A. 1. are continued as follows;

(a) Big Tobacco, by offering free product to the retailer in marketing campaigns, directly creates two for one, (and even three for one!), packs/cartons price discounts which eliminate competition for PMRTP or MRTP by creating an insurmountable financial barrier to market entry by any product newcomer.

(b) The price discounting encourages youth smoking and initiation of youth smoking.

(c) Without a ban, there is a highly reduced incentive for new innovations, which is contrary to the FDA’s IM/NAS funded report recommendations. (Crane, p. 390)

(d) Collectively, cigarette companies can earn greater profits if none of them introduces a modified risk cigarette. Such a cigarette will dramatically diminish their “brand position” asset. “The possibility of innovation-suppressing collusion or exclusionary conduct is apparent.” (Crane, p. 390)

(e) In 2005 smoking consumers were contacted to compare their brand to E’s brand, a new product with replenished d-alpha Tocopherol. Over 750 smokers contacted showed E’s were favored over any established cigarette. Following this, exposure was obtained at national, state, regional and distributor oriented trade shows. In over 850 tests at these venues, with smoking consumers, retail and wholesale store owners and operators, 95% favored E’s over their brand. In 2006-7 the E’s brand, under license from RR, was launched into Virginia, North Carolina and Michigan, under the direction of an experienced marketer from Big Tobacco. Placements were made in 65 locations of various

chain stores and a great number of independently owned stores. Once introduced into a chain store, product movement went immediately to 2.4 cartons per week during the short, initial measuring period. While this may not appear to be much to those outside the industry, such initial movement is phenomenal. The same relative success occurred at non-chain stores. As a result of the success, two major Big Tobacco competitors initiated concentrated action to stifle E sales. Philip Morris and R. J. Reynolds offered "Buy one get one free" directly into retail outlets against E cigarette placements. Nearby retail outlets that had no E placement were void of "Buy one get one free". Petitioner ET had no funds to compete by selling product "two for one" or to finance a challenge to this reportedly illegal, predatory activity. Retreat from the market occurred because of this targeted discounting and the grounds stated in B. 2.

Petitioner prays that the above represents sufficient grounds to act favorably on Action A. 1.

## **2. Grounds for action on A. 2.**

The grounds stated in A. 1. (c) and (d) above are hereby included as grounds for A. 2.

In addition;

(a) Anticompetitive rebate contracts created by Big Tobacco are well known. They are designed to maintain control of their market shares in each store or chain of stores they sell. These contracts force retailers to maintain a Big Tobacco company's product market share in the chain/store or face a large rebate penalty. As an example, E's was initially placed in 19 stores of a 60 store chain. With pressure from a Big Tobacco company, it was reported the chain obtained over \$300,000 in rebates as a result of dropping E's product placement sales.

Further, a woman smoker switched to smoking E's for its benefits, but her husband's own very large tobacco outlet chain could not introduce or carry E's because of the threat of a rebate loss that reportedly could be over \$2 million. The rebate penalty practiced by Big Tobacco bars entry of new products into the marketplace. There is no incentive for innovators to introduce PMRTP or MRTP in the face of this practice. PMRTP or MRTP entry into the marketplace is impossible without a ban on the rebate penalty practice.

Petitioner prays that the above represents sufficient grounds to act favorably on Action A. 2.

### 3. Grounds for Action on A. 3.

“The most difficult subjects can be explained to the most slow-witted man if he has not formed any idea of them already; but the simplest thing cannot be made clear to the most intelligent man if he is firmly persuaded that he knows already, without a shadow of doubt, what is laid before him.” L. N. Tolstoy, 1894.

Author felt the need to mention the above quote based on his experience trying to communicate with the exclusionary tobacco industry.

(a) Vitamin E, naturally occurring in tobacco as d-alpha-Tocopherol (AT) is oxidized, metabolized and lost in the processing and production of tobacco products. The AT level starts at  $\approx 800\text{-}1200\mu\text{g/g}$ , when cured aged and cut prior cigarette mfg. falls to less than  $\approx 600$ , then only to  $\approx 390\mu\text{g/g}$  or less when made into a stick. ( $\approx 334\mu\text{g}$  in a 0.85g stick) This is almost all lost when smoked as evidenced in MS-CSC and SS-CSC levels. The 1R4F cigarette starts with  $\approx 334\mu\text{g/g}$  in an unburned cigarette yielding only  $\approx 8\mu\text{g}$  in its MS-CSC and  $\approx 2\mu\text{g}$  in its SS-CSC.

(b) Tobacco smoke and its condensates are known to cause long-term chronic irritation in all smokers. There is evidence and the causal relationship is well known that chronic irritation damages tissues.

“Johns Hopkins researchers say there is growing evidence that stem cells gone awry in their efforts to repair tissue damage could help explain why long-term irritation...can create a breeding ground for certain cancers.” ... “Chronic irritation damages tissues...That damage triggers a repair process that requires tissue-specific stem cells to gather, multiply and eventually replace the damaged cells.” ...“However, if recurring irritation and damage prevent the repair’s completion...[the] co-authors...suggest that chronic irritation might facilitate trapping of stem cells in a state of perpetual activation, and subsequent genetic or other changes in the cells may send them over the edge.”

[www.hopkinsmedicine.org/Press\\_releases/2004/11\\_22\\_04.html](http://www.hopkinsmedicine.org/Press_releases/2004/11_22_04.html)

(c) Petitioner RR discovered replenishment via stabilized AT in cigarettes dramatically and demonstrably reduces chronic irritation caused by MS-CS and SS-CS. The effect is stunning. Cognitive sensory discrimination is the basis of the finding. Each member of The Tobacco Products Scientific Advisory Committee can personally make the same finding and it applies to all tobacco products. The replenishment can dial in any MS-CSC levels, for example, commercial E’s brand

AT up to approx. 350µg per stick. The resultant relative SS-CSC is replenished up to approx. 45µg of AT per stick.

(d) In arriving at the AT replenished CSC levels, no oxidized forms of Tocopherol are present. In the burned cigarette, the stabilized AT disassociates to natural AT vapor (≈82%) and Succinic acid (≈18%), both phytochemicals natural to tobacco and human diet. [www.plantphysiol.org/cgi/reprint/16/4/771.pdf](http://www.plantphysiol.org/cgi/reprint/16/4/771.pdf)

Succinic acid, natural to plant and animal tissues, is a slightly stronger acid/antioxidant than ascorbic acid (vitamin C) and may team with AT similar to vitamin C. In nutraceutical form as a food additive and dietary supplement, it is safe and approved by FDA. Stabilization is required to avoid stick aging loss of AT in a matter of weeks.

The effects of replenished AT in tobacco products;

- Reduces irritation- the demonstrably novel impact of the technology is to greatly and dramatically reduce the irritation and its after effects caused by smoking cigarettes. Reduced and/or elimination of, “smoker’s hangover.” Smoke induced chronic cough and smoker’s throat/voice (hoarse-ness/raspiness) is well known. During product sale period petitioner documented diminished smoker’s cough and hoarseness.
- Reduction of stale tobacco odor- everyone has experienced the stale tobacco odor on smoker’s clothing, in autos, bars and on household furnishings. Such odor is, demonstrably, substantially reduced.
- Less offensive to non-smokers as a result of reduction in irritation and odor.

The FTC approved E’s brand packaging and (verbally) considered the AT replenishment related to smokers infinitesimal. While not approving claims using AT’s benefits noted above, the FTC allowed making those claims on the packaging and promotional materials. These were not health claims per se but rather fact related to the demonstrable effects of replenishment. RR has been asked by one tobacco manufacturer’s R&D dept. to provide proof other than cognitive sensory differentiation. An analogy would be to ask RR to provide proof that sugar is sweet. In both cases the answer is that the proof is self evident. OSHA has standards to reduce chemical irritants. The FDA can reduce chronic smoke irritation via a minimum AT standard in CSC.

(d) Worldwide patents on this replenishment of stabilized AT technology have been granted to petitioner RR from;

USA, EU (validated in Germany, Switzerland, UK, France, Italy, and Spain), Canada, Mexico, China, Russian Federation, India, Eurasia, Belarus, Indonesia, Singapore, South Korea, Australia, South Africa, Zimbabwe, Kenya and is pending in other countries.

(e) Petitioner RR would be willing to assign this intellectual property to the FDA and /or WHO and/or a consortium of University research groups such as Lombardi Cancer Center, Georgetown U., UCSF Center for Tobacco Control & Education, OHSU and others, and /or Tobacco Free Kids and/or other worthy organizations the FDA recommends, all with the provision that royalties be used to promote modified risk and smoking cessation.

(f) On the subject of those who want to deny smoker's a modified risk (reduced harm) product, previously cited Crane, at p. 386, reviews the matter succinctly. If chronic irritation of smokers can be diminished in all tobacco products and infer smoker's disease and death reduction, should this be denied the smoking public? Petitioner hereby includes cited Crane's Section IV, ppg. 386-392, and p.406 as part of Grounds B. 3. (f).

(g) The history of Big Tobacco's search for a reduced harm cigarette is a matter of record. Citing Crane, p. 368, "...many of the States and some private plaintiffs have alleged that over the course of decades, the dominant firms colluded to suppress development of safer cigarettes, thereby increasing the harms of smoking over what they would have been in a competitive market...market participants may have incentives to suppress competition for less harmful forms of consumption."

Petitioner prays that the above represents sufficient grounds to act favorably on Action A. 3.

#### **4. Grounds for Action on A. 4.**

(a) The grounds stated in B. 1. (e), and B. 3. (a), (b) and (c) and the grounds stated in A. 3. are hereby incorporated as grounds for Action on A. 4.

(b) There is not a shred of doubt in the medical community that smoking causes long term mouth, throat and lung irritation...and ultimately causes cancer, heart disease, emphysema and many other serious diseases. Every medical doctor knows, as fact, that such chronic (long term) irritation causes bio-mayhem.

(c) Replenishment of stabilized AT in cigarettes is a logical, uncomplicated, readily available technology to quickly establish the first PMRTP. It would create a reduced chronic irritation product foundation for the FDA upon which future meaningful modified risk changes can be built upon.

(d) It appears that past and current efforts to achieve MRTP are focused on reducing or eliminating suspected carcinogens and toxins by modifying the tobacco, removal of specific toxins (nitrosamines, formaldehyde, etc.) or using microbial assays for claiming increased anti-mutagenicity. (Some compounds, like benzo[a]pyrene are not mutagenic by themselves, but their metabolic products are.)

The number of chemical constituents in tobacco is estimated to exceed 8,000 and in tobacco smoke, over 7,000. The complexity is so great that claiming modified risk with all the so called PREPs to date has been challenged as conjecture. A study by Dr. James F. Pankow of OHSU concludes that the removal of known toxins with promises of reduced harm based on such removal "speculative and unverified." Quoting Pankow, "Despite all the years of research, we can only account for a small percentage of carcinogenicity of smoking conventional cigarettes." ..."Since we can't account for the risks from smoking conventional cigarettes, it does not accomplish much to just remove a few of the known toxins."

[www.ohsu.edu/ohsuedu/newspub/releases/031607cigarettes.cfm](http://www.ohsu.edu/ohsuedu/newspub/releases/031607cigarettes.cfm)

(e) Petitioner believes that a more yielding answer to harm reduction lies not only in reducing some individual toxins but rather the answer primarily lies in mediating the totality of irritation-inducing chemical moieties (molecular functional and, more so, molecular functional groups as substructures) involved in tobacco use. Smoke and its condensates create the chemical assault that causes chronic irritation. The irritated smoker's tissues create their own biochemical moieties in defense, beginning with irritation defense and then complexed with damage repair moieties. Thus, the ongoing environment of chronic irritation, chronic biochemical defense to the irritation and chronic repair to the irritation's damage becomes overwhelming and may well be the major tobacco related

disease process. Logic and medical experience affirms that if one reduces chronic irritation (a precursor) to disease, one reduces the disease.

Replenished AT in E's brand, by reducing irritation, is a PMRTP. Recognizing this is an uncomplicated first step the FDA can take to potentially modify risk for smokers, particularly since E's brand has already been introduced to the market. Millions of E's brand cigarettes have been favorably smoked by the public.

The effects of AT replenishment can be demonstrated to each and every member of the Tobacco Products Scientific Advisory Committee. They can personally experience what tobacco irritation is, its extent, by product type and have cognitive sensory discrimination to use as a tool to make judgments on products placed before them, such as replenished AT. By analogy, would such a committee in enology be able to form valid judgments without the use of cognitive sensory discrimination?

(f) Interestingly, in addition to the effects described above, the replenished AT also changes the reflux species to a lighter color in a smoked stick. This can be seen in the lighter colored condensate in a puff vs. a control on a sheet filter such as tissue or towel paper. The effect is the same for bidis and for smokeless saliva leachant. (Bidis are banned in some states. They are dramatically more irritating than conventional cigarettes.)

(g) Prior to market introduction, in 2003, toxicity testing was conducted under the direction of Dr. Chandra (Gary) Gairola, who at the time was Professor of Toxicology, Graduate Center for Toxicology, University of Kentucky, Louisville, KY. Animal exposure studies, AT condensate measurements and other cigarette physical measurements were conducted under his guidance. Ames testing was done by an outside laboratory.

1. Animal testing was conducted using side stream smoke exposure using "full flavor" commercial cigarettes made by a major cigarette manufacturer. The SS-SC of the control had 2 $\mu$ g/stick of AT vs. one replenished at 46 $\mu$ g and one replenished at the 102 $\mu$ g level. According to the National Cancer Institute, because side stream smoke escapes without passing down the tobacco column and through a filter, side stream smoke differs in composition from mainstream smoke, containing higher concentrations of a number of constituents, including more than twice as much carbon monoxide, almost twice as much tar and nearly three times as much nicotine and 10-40 times the levels of amounts of nitrosamines. The ultimate goal of the testing was to determine if AT replenishment would incur adverse effects. There were no adverse effects.

2. Dr. Gairola tested whole body exposure to side stream (SS) smoke exposed mice for 4 hours/day, for 5 days /week...6, 12 and 24 weeks. All animals survived to their end point. Of interest was  $\approx$  25% less Mn-RET frequency percentage vs. control, at 22 weeks for AT replenished exposure. Thus, potential reduced genotoxicant-induced micronuclei. Inflammatory lung response showed no differences in 6 and 12 weeks. Atherosclerosis in apoe<sup>-/-</sup> mice showed no differences in plaque levels at end point.

Six month old cigarette MS-CSC DNA interaction polar adduct activity preliminary testing showed 100 % dose responsive reduction of polar adduct activity for AT replenished vs. control. Old cigarettes (12 and 18 months old) cigarette MS-CSC DNA interaction using different assay test methods showed variability in results from insoluble constituents falling out when added to the aqueous reaction mixture. Sample accuracy also came into question in the older tests. The effect of AT replenishment begins to diminish beginning after 6 months due to aging of the sticks and at approx. 9-10 months age the stick returns to the irritation level of a newly made conventional cigarette.

3. Ames mutagenicity testing showed no differences. The test is unrelated to AT functionality with respect to mutagenic irritation.

4. AT disappears faster in smokers and there is a deficiency of AT in smokers lungs. AT's value is summarized in "Oxidants, Antioxidants and Respiratory Tract Lining Fluids" Cross et al., p. 187.  
[www.ncbi.nlm.nih.gov/pmc/articles/pmc1566988/pdf/envhper00409-0183.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/pmc1566988/pdf/envhper00409-0183.pdf)

5. ET's licensee is a very small tobacco product manufacturer (STPM). The Big Tobacco industry will claim it cannot run stabilized AT replenished product on some of its machines (Hauni Protos). It easily runs on Molins stick makers. ET's licensee has decades of experience at Big Tobacco and has machine technique solutions for Hauni machines. RR also has technology to overcome the objection. The industry will object to mixing powder into tobacco. RR has technology to fit stabilized AT into their traditional liquid spray blending methods.

Petitioner prays that the above represents sufficient grounds to act favorably on Action A. 4.

**C. Environmental Impact**

Claim for categorical exclusion under 21 C.F.R. 25.3 is hereby made and therefore this petition does not require an EA or EIS.

**D. Economic Impact**

Required only when requested by the Commissioner following review of the petition.

**E. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

The undersigned submits this petition on behalf of Rousseau Research, Inc., and ETOBACCO LLC.

Joseph D. Russo  
Chairman  
Rousseau Research, Inc., and  
ETOBACCO LLC  
3122 Bandera DR., Palo Alto, CA 94304  
Phone 650-949-4510 jrussoceo@earthlink.net