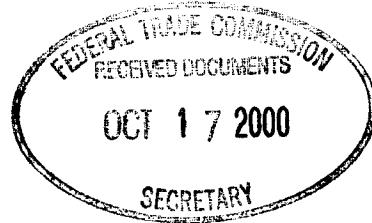

UST

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BY E-MAIL & FEDERAL EXPRESS

October 16, 2000



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

Re: 16 CFR Part 307 – Public Comments on
Regulations Implementing the Comprehensive
Smokeless Tobacco Health Education Act of 1986

Dear Mr. Secretary:

This submission on behalf of United States Tobacco Company (USTC) is in connection with the Federal Trade Commission's (FTC) request for comments regarding the regulations implementing the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA") and is intended to comment on the carefully orchestrated yet duplicative submissions from various federal, state and private health entities.

This submission is not intended to correct the numerous misstatements of law and fact in those submissions, nor to challenge the methodologies used in unpublished studies by The Centers for Disease Control and Prevention (CDC) and studies by the Massachusetts Tobacco Control Program.

As a general matter, USTC notes for the record that many submissions cite studies and statistics related to cigarette smoking (both U.S. and foreign) to justify changes to the regulations regarding smokeless tobacco products -- a questionable foundation under any analysis.

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More specifically, those submissions focus primarily on two issues as justification for disproportionate revisions to the current regulations governing smokeless tobacco products: (1) concerns regarding youth usage of smokeless tobacco products and (2) the alleged health consequences associated with smokeless tobacco use. Each of these claims is addressed in detail.

(1) Youth Usage of Smokeless Tobacco Products

USTC's longstanding policy is that its smokeless tobacco products are for adults, and adults only. As a responsible corporate citizen, USTC has been dedicated to addressing concerns about youth usage of smokeless tobacco products.

Most recently, in addition to other initiatives historically, USTC became the only smokeless tobacco manufacturer to enter into an agreement -- the Smokeless Tobacco Master Settlement Agreement (STMSA) -- with 45 State Attorneys General. Under the agreement, USTC adopted an array of marketing and advertising restrictions directly addressing public health concerns regarding youth access to smokeless tobacco products. In addition, USTC will provide up to \$100 million over a 10-year period to the American Legacy Foundation, which will use the money to conduct public education campaigns and other programs to reduce under-age tobacco use and substance abuse. Notably, there is evidence that this initiative, in addition to others done in cooperation with retailers, adult consumers and other responsible adults, is achieving results.

The following studies report a significant decline in youth usage of smokeless tobacco products:

- Healthy People 2000, which relies on data from the National Household Survey on Drug Abuse conducted by the Substance Abuse and Mental Services Administration of the U.S. Department of Health and Human Services
- Youth Risk Behavior Surveillance Survey, conducted biennially by the Centers for Disease Control of the U.S. Department of Health and Human Services
- Monitoring the Future Study, conducted annually by the University of Michigan's Institute for Social Research

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Despite differences in reported use, all three studies confirm that smokeless tobacco usage by minors is on a downward trend. Attached to this submission is a copy of USTC's brochure, "Moving In The Right Direction," which graphically illustrates this decline, which differs dramatically from youth usage data regarding other tobacco products.

Clearly, the claim that youth usage of smokeless tobacco use "has reached almost epidemic proportions" is without basis in fact and provides no justification for revising the current regulations regarding smokeless tobacco products.

(2) Smokeless Tobacco and Health

The second justification cited in many submissions for radically revising the current regulations is the claim that use of smokeless tobacco products "represents a significant health risk" so as to warrant labeling changes to "have significant impact on reducing use of this deadly product."

However, a complete and careful analysis of the epidemiological and experimental data relating to smokeless tobacco and cancer does not support those claims. Also attached to this submission are two submissions dated October 1997 and February 1999 to the National Toxicology Program which incorporate the requisite analyses. Among the analyses submitted in October 1997 is one by Dr. Kenneth D. MacRae, who was at that time a Reader in Medical Statistics at the Imperial College School of Medicine of the University of London, a fellow of the Royal Statistical Society and a member of the editorial committee of the British Medical Journal. Dr. MacRae reviewed the epidemiological data relating to smokeless tobacco and cancer, and concluded as follows:

"It is my opinion that the epidemiological data do not support the conclusion that smokeless has been shown to be a cause of cancer in humans. Nor, in my opinion, does the epidemiological data, taken as a whole, support a finding that use of smokeless tobacco is a risk factor for oral cancer."

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The validity of Dr. MacRae's conclusion is underscored by two case-control studies relating to smokeless tobacco and oral cancer which were published in 1998 and incorporated in the February 1999 submission. Both case-control studies were carried out in Sweden where a substantial portion of the adult population is reported to use smokeless tobacco. Both studies reported that there was no significantly increased risk of oral cancer associated with the use of smokeless tobacco in their study populations.

The analyses also included an extensive review by Professor Paul Grasso and his colleagues at the School of Biological Sciences, University of Surrey (U.K.) of the scientific literature in order to examine the experimental evidence relating to smokeless tobacco and cancer. Based on their assessment of the relevant data, Prof. Grasso and his colleagues concluded:

"Overall, the experimental studies support the conclusion that smokeless tobacco is not carcinogenic in the oral cavity of laboratory animals."

Clearly, the claims regarding the alleged health consequences of smokeless tobacco use, cited to justify radical revisions to the current regulations, are not substantiated by the scientific data.

Any action by the FTC to revise the current regulations regarding smokeless tobacco products must be based on law and fact, not unsubstantiated protestations by public health activists about an unfavored consumer product. Based on the facts, the science and the law, any significant changes to the current regulations are unwarranted.

Sincerely,



Richard H. Verheij

RHV:jp

Moving In The Right Direction



United States Tobacco Company

UNITED STATES TOBACCO COMPANY
Meeting our Responsibilities as a Corporate Citizen

SMOKELESS TOBACCO PRODUCTS ARE NOT FOR SALE TO MINORS

At U.S. Tobacco Company, this is our policy, and it's not open to interpretation.



From Our Statement Of Corporate Principles:

"U.S. Tobacco Company is committed to complying with the provisions of the Smokeless Tobacco Master Settlement Agreement and remains firm in its belief that smokeless tobacco should be for adults only. The Company will continue to pursue and adhere to policies that support and realize this belief."

There is evidence that these initiatives and other efforts are working.

The graph represents the declines in youth usage reported by:

- ◆ Healthy People 2000
- ◆ Youth Risk Behavior Surveillance Survey
- ◆ Monitoring the Future

Despite differences in reported use, all three studies confirm that smokeless tobacco usage by minors is on a downward trend. That's moving in the right direction.

There is no easy answer to the challenge of reducing youth usage of smokeless tobacco products. We at U.S. Tobacco Company are committed to continually moving in the right direction with our policy and programs to discourage sales to minors.

Meeting Our Responsibilities As A Corporate Citizen

Every day U.S. Tobacco Company demonstrates our commitment to discouraging sales of smokeless tobacco products to minors. The Company supports, participates in, and creates initiatives designed to keep our products out of the hands of youth.

- ◆ **Partnership with the States**
 - ◆ In November 1998, U.S. Tobacco Company became the only smokeless tobacco manufacturer to reach an agreement with 45 State Attorneys General. Under this agreement, known as the Smokeless Tobacco Master Settlement Agreement (STMAs), the Company adopted an array of marketing and advertising restrictions, and agreed to help fund a national public health foundation dedicated to significantly reducing the use of tobacco products by youth.
 - ◆ **U.S. Tobacco Company remains the only smokeless tobacco company in the country participating in this agreement.**
 - ◆ Elements of U.S. Tobacco Company's partnership with the States include the following:

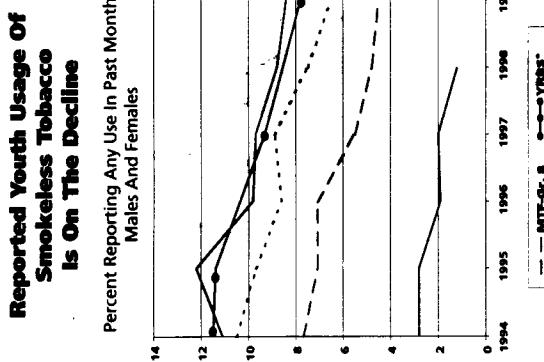
- ◆ U.S. Tobacco Company will provide up to \$100 million over a 10-year period to the American Legacy Foundation. This foundation will use the money to conduct public education campaigns and other programs to reduce underage tobacco use and substance abuse.
- ◆ U.S. Tobacco Company also adopted the following advertising and promotional restrictions.
- ◆
 - ◆ No direct or indirect targeting of youth (persons under 18 years)
 - ◆ No outdoor advertising (including billboards)
 - ◆ No signs in arenas, stadiums, shopping malls, and video arcades
 - ◆ No transit advertising

Promotional Restrictions

- ◆ **No Brand Name Sponsorships of:**

- Concerns
 - Events in which youths are a significant portion of the audience
 - Events in which paid participants or contestants are youths
 - Football, baseball, soccer, basketball and hockey
 - No distribution of non-tobacco merchandise bearing the brand name, logo, or trademark of a tobacco product to the general public.
 - ◆ No distribution of free samples, ETC! in an ADULT ONLY FACILITY or in a location with a purchase-as-a-rebate.

Code or magnetic strip on driver's license, enabling sellers of tobacco products to determine whether the printed information on the front has been falsified. Four states (New York, Oklahoma, Vermont, and Wyoming) have already enacted legislation encouraging the use of those electronic scanning devices.



HP: Healthy People 2000 National Household Survey on Lung Disease. Conducted annually by the National Center for Health Statistics. A nationally representative sample of the U.S. population aged 12 and over. YRBS: Youth Risk Behavior Surveillance Survey Conducted biennially by the Centers for Disease Control of the U.S. Department of Health and Human Services. * 1991-Data from Survey conducted in 1995 and 1996	MIF: Monitoring the Future Study Conducted annually by the University of Michigan.
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