

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

ARGEO PAUL CELLUCCI
Governor

JANE SWIFT
Lieutenant Governor

WILLIAM D. O'LEARY
Secretary

HOWARD K. KOH, MD, MPH
Commissioner

October 3, 2000

Honorable Robert Pitofsky
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Chairman Pitofsky:

The Massachusetts Department of Public Health respectfully requests that the Federal Trade Commission (FTC) initiate an investigation into the advertising of the RJ Reynolds Tobacco Company's (RJRTC) Eclipse product pursuant to section 5 of the Federal Trade Commission Act (15 U.S.C. 45). Eclipse is being advertised on its website www.RJRDIRECT.com, which makes the product available to any Massachusetts resident for purchase.

Eclipse is a nicotine delivery system that RJRT is marketing as a novel cigarette that reduces a smoker's risk to disease including cancer. In its advertising, RJRT makes a number of claims about how Eclipse lowers smokers' exposure to certain toxins. Our Department has carefully reviewed the advertising claims made for Eclipse on the company's website and has commissioned independent research comparing toxic emissions in the smoke of Eclipse to toxic emissions in two ultralight cigarette brands, Now and Carlton. Based on our research, we are concerned that smokers, former smokers and young non-smokers may be misled into thinking that Eclipse is a safe alternative to conventional cigarettes.

To protect the public's health, the FTC should carefully review RJRTC's advertising and marketing practices before the product is sold directly in Massachusetts and other states, and/or seek a temporary or permanent injunction pursuant to section 13(G) of the Federal Trade Commission Act [15 U.S.C. 53 (G)].

1. RJR Smoke Constituent Research

The RJRT website contains a chart summarizing data on the smoke constituents of Eclipse and compares those emissions to those of a "typical" ultralight cigarette, Merit Ultralight, and makes the claim "There is No Cigarette like Eclipse."

**Table 1 (From RJRT website)
"Why There's No Cigarette Like Eclipse"**

	Typical Ultralight	Eclipse	Difference
Tobacco Burned	636 mg	15 mg	97% less
Comparing Smoke Components			
Tar* and Nicotine	4.7 mg	0.8 mg	83% less
Vs.			
Water and Glycerin (simple smoke components)	0.8 mg	3.3 mg	313% more
Carcinogens**	0.68mg	0.13 mg	80% less
Secondhand Smoke***	0.18 mg/m3	0.03 mg/m3	82% less
Carbon monoxide	5.4 mg	6.3 mg	17% more

A Merit Ultralight was tested as the typical ultralight. *FTC "tar" minus glycerin. **Under FTC conditions, RJRT measured 14 compounds in cigarette smoke that appear on one or more of the following lists of known, probable or possible human carcinogens: International Agency for Research on Cancer, National Toxicology Program, and Environmental Protection Agency. Acrolein was no different. Of the dozens of compounds measured in Eclipse smoke, one (furfural) shows an increase. ***Based on smoke particles.

In Table 1, RJRT makes a number of claims that Eclipse has far less toxins in the smoke when compared to a "typical ultralight." The most notable is the claim of 80% less carcinogens in the smoke. The website provides additional data supporting this claim and reports on the levels of 14 carcinogens in Eclipse and Merit (see Appendix 2). Table 2 presents data from the list on five of the most potent carcinogens, and with the exception of acrolein, the levels found in Eclipse are between 64% and 87% less than Merit.

Table 2
FTC/ISO Conditions

Toxin	Eclipse	Merit	Difference
Tar	3.2	5.3	40% less
Nicotine	0.18	0.47	62% less
CO	7.5	6.5	15% <i>more</i>
Acetaldehyde (ug)	75	311	76% less
Acrolein (ug)	33	35	6% less*
BaP (ng)	0.6	4.0	86% less
NNN (ng)	20	148	87% less
NNK (ng)	23	63	64% less

Source: RJR website www.eclipse.rjrt.com

*No statistical difference ($p \leq 0.05$)

According to Table 2, Eclipse has 76% less acetaldehyde (75 ug vs. 311 ug), 86% less BaP (0.6 ng vs. 4.0 ng), 87% less NNN (20 ng vs. 148 ng) and 64% less NNK (23 ng vs. 63 ng). Acrolein levels were approximately the same. The website data appears to support RJRT's claim that "There's no cigarette like Eclipse" and the company relies heavily on this data to make numerous claims about how Eclipse reduces cancer risk elsewhere on the website and in press releases.

2. How RJRT Uses This and Other Data to Make Health Claims

RJRT makes a number of claims on the website on the health benefits of smoking Eclipse, of which the following are just a few.

- Eclipse may present less risk of cancer.
- Eclipse produces less inflammation in the respiratory system, which suggests lower risks of chronic bronchitis and possibly even emphysema.
- Eclipse reduces second-hand smoke by 80%.
- Eclipse contains far less of many of the compounds that are believed to contribute to the risk of cancer.
- Eclipse may pose less risk to smokers of developing cardiovascular disease.

RJRT makes specific claims on smoke carcinogens and reductions in cancer risk.

We have also reviewed RJRT's press releases, website and promotional literature and have found the following explicit and implied claims that relate to carcinogens in the smoke of Eclipse and cancer risk. These claims are allegedly supported in whole or part by the results of the smoke testing study referenced above.

- Compared to other cigarettes, the smoke from Eclipse: "Contains 80 percent lower concentrations of many known, probable, and possible carcinogenic smoke compounds."
- "Produces 90 percent fewer skin tumors in mice."

- "Contains far less of many of the compounds linked to smoking-related diseases, which translates into substantially lower levels of smoke toxicity. The results of an extensive battery of tests on Eclipse are striking."
- "This is for smokers who have been waiting for a cigarette that respond to certain smoking-related illnesses. Including cancer."
- "Extensive scientific studies show that compared to other cigarettes: Eclipse may present less risk of cancer."
- "Eclipse contains far less of many of the compounds found in cigarette smoke that are believed to contribute to the risk of cancer and other illnesses."

3. Is There Really "No Cigarette Like Eclipse": A Comparison of Eclipse to Now and Carlton Ultralight Cigarettes

To validate RJRT's claim that Eclipse has 80% lower levels of carcinogens in smoke when compared to a typical ultralight cigarette (Merit), the Massachusetts Department of Public Health commissioned independent research with Labstat of Canada, a certified cigarette testing laboratory that periodically does smoke constituent testing for RJRT, to compare Eclipse smoke to that of two other ultralight products, Now and Carlton. (Characterization of Three "Low/Ultra Low" Tar Brands, September 6, 2000, Labstat International Inc.) Ultralight products range in FTC tar levels from approximately 0 – 5 mg per cigarette. The brands tested in this study were Now King Size Hard Pack, with less than .5 mg tar, and Carlton King Size Soft Pack, with 1 mg tar.

Two testing methods were chosen: first, the FTC/ISO method, and second, a more intensive method where the puff volume was increased from 35 ml (FTC) to 50 ml, and the puff frequency decreased from 60 seconds to 30 seconds. These are the same methods employed in the 1996 RJRT presentation to the Tobacco Chemists Research Conference (Borgerding MF, Bodnar JA, Chung HL, Morrison CC, Risner CH, et al. Investigation of a new cigarette which primarily heats tobacco using an alternative puffing regimen).

Table 4
Smoke Carcinogens in Eclipse vs. Carlton and Now

	Eclipse	Carlton	% Change	Now	% Change
Acetaldehyde (ug)	84.2	99.8	16% less	10.1	734% more
Acrolein (ug)	11.5	10.4	15% more	2.0	475% more
BaP (ng)	1.2	1.3	8% less	(.48)*	Level too low to quantify.
NNN (ng)	26	34.0	24% less	(4.28)*	Level too low to quantify.
NNK (ng)	31.8	(23.5)*	Level too low to quantify.	(4.49)**	Level too low to quantify.

Source: Labstat International

*NQ—Not quantifiable

**BDL—Below the detection limit

According to Table 4, Acetaldehyde levels in Eclipse were slightly less (16%) than in Carlton (84.2 ug vs. 99.8 ug) but 734% more than in Now (84.2 ug vs. 10.1 ug). Acrolein levels in Eclipse were similar to Carlton (11.5 ug vs. 10.4), but Eclipse had 475% more acrolein than Now (11.5 ug vs. 2.0 ug). Eclipse had a similar amount of BaP to Carlton (1.2 ug vs. 1.3 ug), while BaP levels in Now were not quantifiable (too low to be assigned a meaningful value). NNN levels were 24% less in Eclipse than Carlton, but were not quantifiable for Now. NNK levels were not quantifiable in Carlton and were not detectable in Now; in both, levels were significantly lower than Eclipse (31.8 ng). Eclipse does not appear to have 80% less cancer causing agents in its smoke compared to these two ultralight products.

This research strongly suggests that “there really are cigarettes like Eclipse” including Carlton and Now. In fact, Eclipse may have much higher levels of known carcinogens than Now, a product that is already in the marketplace and being sold without explicit health claims. In light of the Department's research, the RJRT claim that Eclipse has 80% less carcinogens in the smoke versus the typical ultralight appears to be false and misleading. Further, the use of RJRT's data to make health claims about reduced risk to cancer also appears to be false and misleading. The data from the Department's study strongly supports action by your agency to have both the tests and the claims made by RJRT independently reviewed and validated by scientific bodies.

4. RJRT's Claims Based on Animal Studies May Be Misleading (Due to a Comparison with Full Flavor Low Tar Cigarettes Rather than Ultralight Cigarettes).

In addition to smoke and smoke constituent testing, RJRT reports selected results from a battery of tests on Eclipse including genetic toxicology, cytotoxicity, animal studies, and human smoker studies. Based on these tests, the website makes the following claims about Eclipse:

- Eclipse produces 90% fewer skin tumors in animal studies.
- Animal inhalation assays demonstrate a decreased pulmonary inflammatory potential in Eclipse.

The animal studies were performed by comparing the Eclipse cigarette to a reference “full flavor low tar cigarette with a smoke yield of approximately 9 mg of tar. The studies did not compare Eclipse to an ultralight reference or commercial ultralight cigarette as was done for other RJRT studies. While the number of tumors produced in skin painting was significantly higher for the reference cigarette, Eclipse did produce a significant number of tumors at higher doses (in 12 out of 40 animals, versus 36 out of 40 for the reference cigarette.) These results may not provide a clear indication of how Eclipse compares to a standard reference ultralight or a commercial ultralight product such as Merit, Carlton, or Now.

Animal inhalation assays were also performed against the “full flavor low tar” 9 mg tar cigarette. Although the summary of this research suggests that “Eclipse generally showed fewer and less severe smoke-related changes,” there were similar results between the Eclipse and the reference cigarette in chronic active inflammation of the larynx and acute inflammation of the ventral larynx. Again, no ultralight reference or ultralight commercial cigarette was included in the study, throwing into question the comparative value of these results.

5. Changes in Smoke Constituents: Premier (1988), Eclipse I (1996), and Eclipse II (2000)

Table 5 presents data of toxic smoke constituents for Premier (the precursor to Eclipse, test-marketed in 1988); the Eclipse product test marketed in 1996 in Chattanooga, Tennessee; and the most recent version of Eclipse introduced in the year 2000 and available now over the Internet (Appendix III). The data were collected from a variety of sources, including the 1988 RJRT Premier Monograph (*New Cigarette Prototypes That Heat Instead of Burn Tobacco*), the 1996 RJRT presentation to the Tobacco Chemists' Research Conference, and the 2000 Labstat study for the Massachusetts Department of Public Health. Similar testing conditions were employed in each of the studies. The data strongly suggests that the levels of certain carcinogens may have increased from the Premier product to the Eclipse I product and increased again in the Eclipse II product.

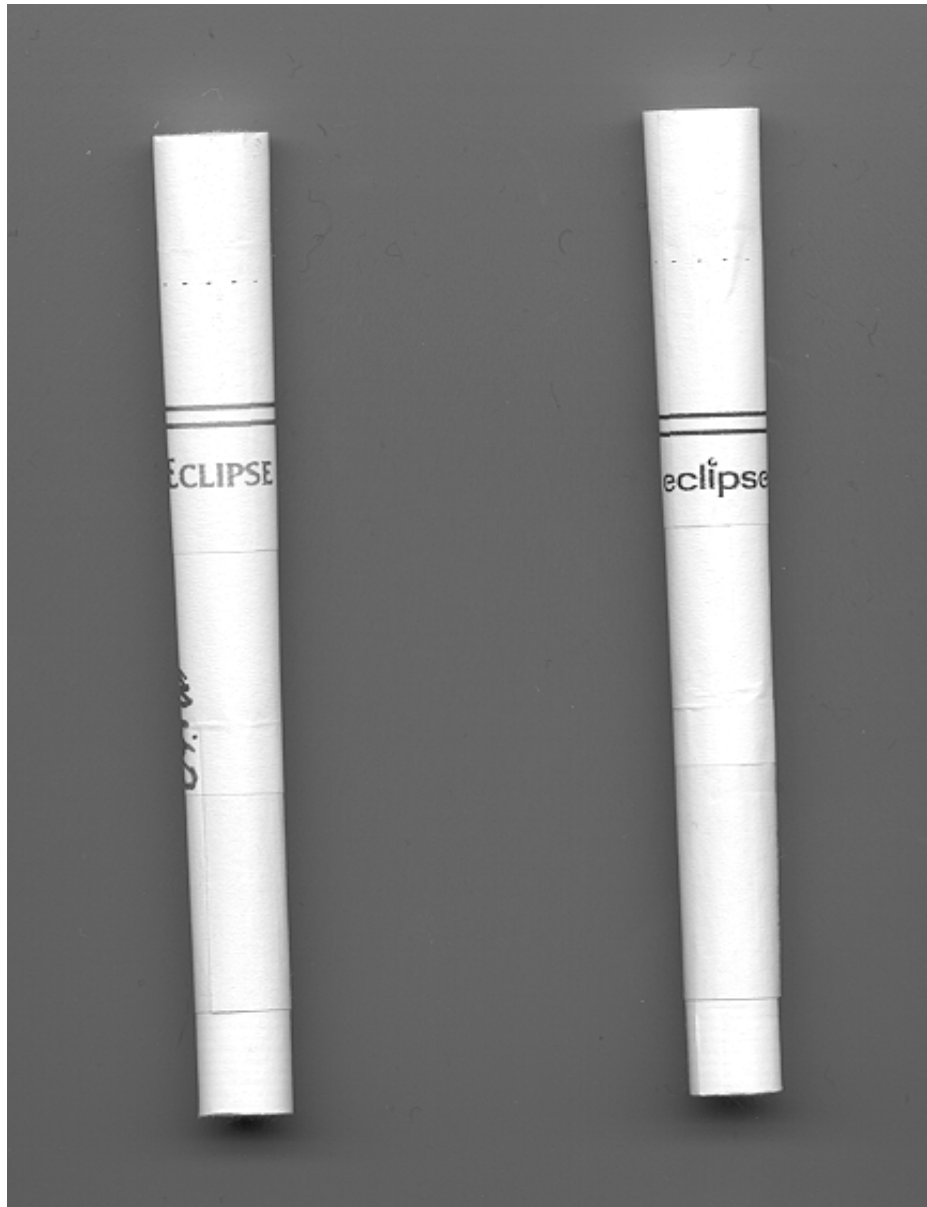
Table 5**Toxic Constituent Levels, Premier/ Eclipse I and II**

	Premier 1988	Eclipse I 1996	% Change Premier	Eclipse II 2000	% Change Eclipse I	% Change Premier
Acetaldehyde (ug)	41	54	+32%	84	+56%	+105%
BaP (ng)	0.08	0.70	+775%	1.20	+71%	+1400%
NNN (ng)	8.5	10.0	+18%	26.0	+160%	+206%
NNK (ng)	2.4	12.0	+400%	32.0	+167%	+1233%

Sources: Premier monograph (RJRT, 1988); TCRC presentation (1996); and Labstat International, Inc. (September, 2000)

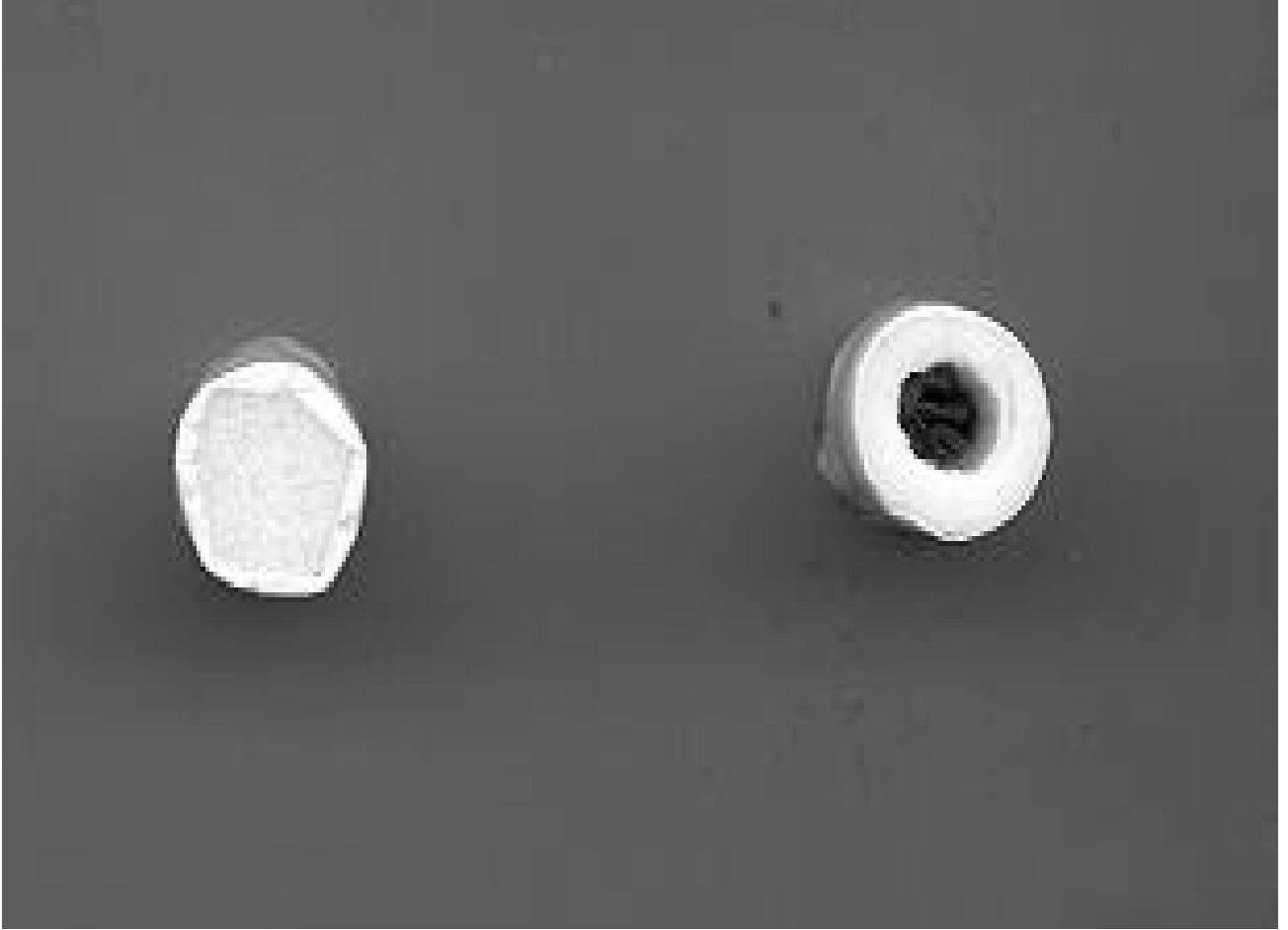
Levels of Benzo[a]pyrene increased 775% from Premier (1988) to the 1996 Eclipse I, and the Eclipse II (2000) product had levels 71% greater than the Eclipse I product. Similar increases were seen for NNN (160% up between Eclipse I and II) and NNK (167% up between Eclipse I and II). The differences between Eclipse I and II may be due to the introduction of a hollow filter into Eclipse II. This may have reduced filtration and resulted in increased levels of toxic smoke constituents.

Changes in Filter Design: Eclipse I (1996) & Eclipse II (2000)



Eclipse
1996

Eclipse
2000



Filter
1996

“Hollow Filter”
2000

Of major concern is that RJRT may be altering the product to make it more acceptable to consumers and in doing so may be increasing the toxicity of the product over time. If this is true, an independent scientific review is needed before Eclipse or like products are redesigned, marketed, or advertised, so that any changes in the products will not increase health risks or mislead the public.

The Department's data indicate that the claims being made for Eclipse are not properly substantiated and that if the product is compared to the range of conventional ultralight cigarettes, a totally different picture emerges for the consumer.

We are well aware the FTC is responsible for taking actions to stop false, deceptive advertising. We believe that the research we have conducted and supplied to the FTC justifies prompt action by your agency.

If you have any questions regarding this letter, please contact Gregory N. Connolly, D.M.D., M.P.H., the Director of our Tobacco Control Program, at (617) 624-5901.

Sincerely,

Howard K. Koh, M.D.
Commissioner

Cc: Attorney General Thomas Riley

**Summary of the Labstat International
Test Report
September 2000**

Standard Conditions

Toxin	Eclipse (926)	Now (848)	Carlton (849)
Tar	4.5	BDL	1.4
Nicotine	.13	BDL	.15
CO	7.4	NQ	1.6
Acetaldehyde (ug)	84.2	10.1	99.8
Acrolein (ug)	11.5	1.96	10.4
BaP (ng)	1.2	NQ	1.3
NNN (ng)	26.0	NQ	34.0
NNK (ng)	31.8	BDL	NQ

BDL – Below the detection limit

NQ – Not quantifiable

Intensive Conditions

Toxin	Eclipse (926)	Now (848)	Carlton (849)
Tar	16.1	.26	5.61
Nicotine	.67	.05	.51
CO	17.3	.56	6.0
Acetaldehyde (ug)	286	41.5	356
Acrolein (ug)	41.5	3.1	30.0
BaP (ng)	3.39	NQ	2.36
NNN (ng)	123	27.3	150
NNK (ng)	128	NQ	76.5

BDL – Below the detection limit

NQ – Not quantifiable