

# CAMPAIGN For TOBACCO-FREE Kids<sup>®</sup>

## NATIONAL CENTER FOR TOBACCO-FREE KIDS

August 1, 2000

Jane Henney, M.D., Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

Dear Dr. Henney:

The National Center for Tobacco-Free Kids and its partners urges the Food and Drug Administration (FDA) to assert jurisdiction over and regulate under the Federal Food, Drug, and Cosmetic Act the marketing, sale and distribution by the RJ Reynolds Tobacco Company (RJRTC) of its Eclipse product. Eclipse has been designed, and is now being marketed, as a risk-reduction product. In its advertising, RJRTC makes various claims touting the health benefits to be derived from Eclipse.

The Center urges you to take steps to stop the further marketing of the Eclipse product in order to prevent harm from its distribution and to minimize the likelihood that RJRTC or other manufacturers will make similar claims about other products. As the enclosed letter from the Society for Research on Nicotine and Tobacco (SRNT) demonstrates, there are insufficient and conflicting scientific data relating to RJRTC's claims about Eclipse. These claims have not been subject to proper scientific review and there is a grave likelihood that consumers will rely to their detriment on these claims. It is essential that the FDA act now to prevent the promotion and distribution of this product, at least until such time as RJRTC's health claims can be adequately reviewed by FDA and evidence can be presented as to the scientific merit of their claims.

RJRTC promotes Eclipse as a new and revolutionary product that departs from traditional cigarette design. RJRTC's advertisements show that the manufacturer intends to prevent and mitigate disease through use of the Eclipse product, for it proudly trumpets the health benefits to be derived from using Eclipse. Consider some of RJRTC's claims in its own advertisements:

- "Eclipse may present less risk of cancer.
- Eclipse produces less inflammation in the respiratory system, which suggests a lower level of chronic bronchitis, and possibly even emphysema.
- Eclipse reduces secondhand smoke by 80%.
- Eclipse reduces carcinogenic compounds.
- Eclipse responds to certain smoking-related illnesses, including cancer.
- Eclipse may pose less risk to smokers of developing cardiovascular disease."

These and other statements clearly show that Eclipse has been designed as, and is certainly being marketed as, a risk-reduction product. Historically, the FDA has acknowledged that the intended use of an article for purposes of the Food, Drug, and Cosmetic Act can be determined by the claims made for it by the seller on the label, packaging, or in advertising.<sup>1</sup> The tobacco industry itself agrees with this position and has repeatedly told the various courts involved in the industry's challenge to FDA's assertion of jurisdiction over traditional tobacco products that intended use, the predicate of a finding of FDA jurisdiction, must be based on promotional claims in labeling, on packaging or in advertising. Those claims are present here. RJRTC's intent – shown unmistakably in its own statements -- in developing Eclipse is to reduce the chances of serious illnesses, including cancer and respiratory diseases, associated with smoking. RJRTC's claims bring Eclipse within the intended use language of the Act and therefore subject to review as a new drug under FDA's jurisdiction.<sup>2</sup>

The FDA has long asserted jurisdiction over products for which health claims<sup>3</sup> are made. Specifically, FDA has consistently asserted jurisdiction over cigarettes marketed with claims that met the statutory definition of a "drug" – i.e.:

"(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals" (21 U.S.C. 321(g)(1)).

In 1959, the since-renamed Federal Drug Administration found that cigarettes containing tartaric acid to reduce the appetite for food were intended to affect the structure or function of the body, and thus were new drugs.<sup>4</sup> Earlier, the FDA had found claims that cigarettes could prevent respiratory ailments were statements indicating intent to treat or prevent a disease, subjecting that product to FDA's jurisdiction.<sup>5</sup> The claims for Fairfax cigarettes, in this latter case, were similar to those made for Eclipse (see attached ad):

Many doctors advise patients who suffer from circulatory diseases, high blood pressure and various heart conditions, to cut down on cigarettes or to stop smoking completely. This is because smoking causes the peripheral arteries to constrict in diameter, thereby diminishing the rate of blood flowing through them. This constriction increases the blood pressure and heart beat. However, the discovery during toxicity tests that inhaling triethylene glycol vapor increases the red blood cell count aroused curiosity as to what reaction the smoking of Fairfax

---

<sup>1</sup> See, e.g., *Coyne Beahm v. FDA*, 966 F. Supp. 1374, 1390. (M.D.N.C. 1997)

<sup>2</sup> See, e.g., *US v An Article of Drug ... Bacto-Unidisk*, 394 U.S. 784; 799 (1969); *Bradley v United States*, 264 F. 79 (5<sup>th</sup> Cir. 1920); *United States v Nutrition Service, Inc.*, 227 F. Supp. 375, 381, 383, 386 (W.D. Pa. 1964), aff'd. 347 F. 2d 233 (3<sup>rd</sup> Cir. 1965); *United States v An Article ... "Sudden Change"*, 409 F. 2d 734, 737 (2d Cir. 1969); and *Estee Lauder, Inc. v FDA*, 727 F. Supp. 1, 2-3 (DDC 1989).

<sup>3</sup> FDA has long used the phrase "health claims" as a short hand for "cure, mitigation, treatment or prevention". See, Reply Brief of FDA, *FDA v. Brown and Williamson Tobacco Corp.*, No. 98-1152 US S.Ct., p. 10.

<sup>4</sup> See *United States v. 354 Bulk Cartons ... Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847, 851 (D.N.J. 1959) (stating that, in light of the manufacturer's appetite suppression claims, the cigarettes seized were drugs within the meaning of the FDCA, 21 U.S.C. 321(g)(1)).

<sup>5</sup> *United States v. 46 Cartons ... Fairfax Cigarettes*, 113 F. Supp. 336, 339 (D.N.J. 1953) (finding that Fairfax Cigarettes fell within the statutory meaning of "drug" as leaflets seized with cigarettes described a "miracle vapor" that could reduce the frequency of respiratory diseases).

cigarettes would have on the circulatory system. Several hundred people were tested on a U.M.A. thermocouple. The findings showed that 91 per cent of those tested disclosed no clinical evidence of any constriction. Test conducted by impartial physicians have substantiated these findings. (Citations omitted)

This position was reiterated in 1972 and 1988, when the FDA Commissioner testified before Congress that cigarettes would be counted as drugs if claims about beneficial physical effects were made on their behalf.<sup>6</sup> Without doubt, RJRTC's statements regarding Eclipse (cited above) are health claims that meet this requirement.

Additionally, those who use cigarettes are addicted to a harmful product. This addiction has been proven by a wealth of laboratory and epidemiological evidence and recognized by every major independent medical organization that has studied the question. As a result of this addiction, cigarette users experience negative effects on the human body, including throat irritation, cancer, and bronchitis. RJRTC's promotional materials for Eclipse claim that Eclipse may mitigate these very effects. RJRTC asserts that Eclipse "may present less risk of cancer," and "produces less inflammation in the respiratory system, which suggests a lower risk of chronic bronchitis". This claimed mitigation is yet another indicator of RJRTC's intent, that brings Eclipse within FDA's jurisdiction.

The FDA must respond to these spurious health claims, or RJRTC's false and misleading statements promoting Eclipse will likely dupe smokers and non-smokers alike. We urge you to take action under the FDA's existing drug and/or device authority to assert jurisdiction over this product and halt these health claims immediately, so as to protect the public health.

There is another and equally valid justification for FDA to assert jurisdiction over Eclipse. The Eclipse product is not a cigarette in any traditional sense and thus not exempt from FDA jurisdiction. It is in fact a novel drug delivery system designed to deliver nicotine, an addictive substance with other pharmacological attributes that has traditionally been regulated by the FDA except when found in traditional cigarettes. There is ample precedent that the presence of a pharmacologically active ingredient, such as nicotine, subjects a product to FDA authority even in the absence of an explicit health claim, if there is appropriate evidence of the manufacturer's intent. Therefore, even if the claims made for Eclipse are not "health claims", the product is properly subject to FDA authority.

The Eclipse is not a cigarette. The product is described by its manufacturer as a unique product that, unlike a cigarette, heats rather than burns tobacco. The product is not a simple roll of tobacco wrapped in paper that when lit burns the tobacco and produces a smoke that is inhaled. In fact, the product does not contain tobacco at all, but uses only shredded tobacco paper. The product itself is contained in a hard casing, not a wrapping of paper or any other substance that burns and is consumed. The tip of the Eclipse is a high-purity carbon tip that is lit and continues to burn, thus providing a

---

<sup>6</sup> See Hearings on S. 1454 Before the Consumer Subcomm. Of the Senate Comm. on Commerce, 92d Cong. 240 (1972); Health Consequences of Smoking: Nicotine Addiction: Hearing Before the Subcomm. on Health & the Env't. of the House Comm. on Energy & Commerce, 100<sup>th</sup> Cong. 17 (1988).

source of heat. The design of Eclipse includes an approximately three-quarter-inch-long tubular aluminum section lying beneath the outer wrapping paper of the device and attached to the fiberglass sheathed heating element tip. The aluminum section functions as a heat-concentrating chamber that appears to be critical for the device to produce an inhalable mixture (aerosol) of nicotine and other substances, and thereby to enable the device to deliver efficiently nicotine into the bloodstream by way of the lungs. When a consumer sucks on the Eclipse tube, the heat from the carbon tip is drawn through the glass-mat heat insulator and then drawn through two areas containing some form of processed shredded tobacco paper. The aerosol that is produced when the consumer sucks on the tube is not smoke, but is composed of approximately 80% glycerol and water. When the consumer is finished with the product, it looks the same as when he/she started -- the tube, the carbon tip, and almost all of the shredded tobacco paper are still there ready to be thrown away. This does not resemble in any way the cigarette, as we know it. The mere presence of shredded tobacco paper in a product is and should not be sufficient to classify the product as a cigarette.

In March, the Supreme Court in *Food and Drug Administration, et al. v. Brown & Williamson Tobacco Corporation, et al.*<sup>7</sup> ruled that the FDA did not have jurisdiction over traditional tobacco products. The primary reason for the Court's finding was its conclusion that Congressional leaders did not intend traditional tobacco products to be included within the Federal Food, Drug and Cosmetic Act. In support of this conclusion, the Court cited various tobacco-related statutes and its mistaken belief that it would be impossible for FDA to regulate cigarettes and smokeless tobacco as traditional drugs or devices under the FD & C Act because the products could not be found to be safe and effective, and adequate directions for their use could not be provided.

The Court did not say that the mere presence of some form of processed tobacco in a product other than a cigarette or smokeless tobacco product defines it as a traditional tobacco product. If that were the case, the manufacturers of the prescription nicotine inhaler could escape FDA oversight by adding tobacco to their current product. Nor can it be argued that, because RJRTC is a major tobacco producer and not a pharmaceutical manufacturer, it is not subject to the Federal Food, Drug, and Cosmetic Act whenever it puts some form of tobacco in its product. For it could as easily put Prozac or steroids in its inhaler and escape FDA oversight by wrapping the product in some tobacco leaf. This clearly was not the intent of either Congress or the Supreme Court.

In addition, unlike a traditional cigarette, this product does not fit nicely into existing tobacco laws and can be properly regulated under the Federal Food, Drug, and Cosmetic Act. For example, RJRTC has made claims about Eclipse that seek to differentiate it from all traditional tobacco products. Moreover, in order for the product to be completely effective, appropriate directions for use should be provided. In both cases (warning labels and directions for use), the FDA -- not the manufacturer -- is the appropriate body to determine their content, after a proper pre-market review of RJRTC's tests and research. Eclipse does not look like a traditional tobacco product, its existence was not contemplated by the legislators who enacted the current tobacco laws, and it needs a different regulatory approach than traditional tobacco products. Thus, it should not be exempt from FDA review because of its tangential relationship to traditional tobacco products.

---

<sup>7</sup> No. 98-1152, 529 U.S. \_\_\_\_\_ (2000).

If Eclipse is not a traditional tobacco product exempt from FDA oversight, then it can be regulated because it contains and delivers nicotine in a pharmacologically active form, and the evidence clearly demonstrates that RJRTC intends for the nicotine in Eclipse to affect the structure and function of the body. It is without doubt that nicotine is highly addictive, and causes other psychoactive effects, such as relaxation and stimulation. These characteristics of nicotine are evidence that the product affects the structure and function of the body. Moreover, FDA already regulates numerous nicotine products (such as nicotine prolicrilix, nicotine inhalers, and nicotine patches), which are intended to assist smokers in quitting and breaking their addiction. These other products fall clearly within the definition of a “drug”.<sup>8</sup> But, even without specific health claims in advertising or on labeling, the existence of nicotine in conjunction with the evidence of the manufacturer’s intent provides justification for an assertion of jurisdiction.

As FDA indicated in its proposal to regulate tobacco products:

“[c]onsistent with the statutory language and Congress’ intent to insure that FDA has the authority to regulate products with non-therapeutic, but pharmacological effects, FDA interpreted the provisions to encompass products that intrinsically have pharmacological effect, even though they are not promoted for therapeutic purposes.”<sup>9</sup>

FDA cited numerous instances in which it exercised authority over products because the intended use could be implied through a known or recognized drug effect of the ingredient (fluoride in toothpaste)<sup>10</sup>, because of evidence of consumer use (khat as a known stimulant narcotic)<sup>11</sup>, because of awareness that a product will achieve pharmacological effects, or because of the totality of circumstances surrounding distribution of the product.<sup>12</sup>

Eclipse is yet another example of a product that falls within the FDA’s jurisdiction because of its composition, its pharmacologically active ingredients, and the use to which it will be put. The Center urges you to take action now to protect public health from this dangerous product.

---

<sup>8</sup> See page 4, above.

<sup>9</sup> 60 Fed. Reg. 41314, 41474 (August 11, 1995).

<sup>10</sup> Id., at 41475.

<sup>11</sup> Id., at 41480.

<sup>12</sup> Id., at 41481-2. See also Id., at 41527 - 0202

Finally, not only should FDA assert jurisdiction, but also it should halt the marketing and advertising of these products until it has had an opportunity to review appropriately these products as new drugs. To have questionable, if not outright false, claims made by Eclipse's manufacturer runs a serious risk that smokers (and potential smokers) will infer from the statements that there are health benefits to be derived from using – or switching to – Eclipse. It has not been proven scientifically that the use of Eclipse would benefit smokers; it is also uncertain whether Eclipse would expose users to wholly new kinds of dangers, such as the inhalation of fiberglass particles. These hazards and potential hazards must be evaluated prior to the distribution of the Eclipse product.

Sincerely,

Matthew L. Myers  
President

American Cancer Society  
American Heart Association  
American Lung Association  
American Medical Association  
Action on Smoking and Health  
African American Tobacco Education Network  
American Academy of Otolaryngology, Head & Neck Surgery, Inc.  
American Academy of Pediatrics  
American College of Cardiology  
American College of Preventive Medicine  
American Medical Student Association/Foundation  
American Medical Women's Association  
American Psychological Association  
American Public Health Association  
American Society of Addiction Medicine  
Campaign for Tobacco-Free Kids  
General Board of Church & Society of the United Methodist Church  
National Association of Local Boards of Health  
New Jersey GASP - Group Against Smoking Pollution  
Oncology Nursing Society  
Partnership for Prevention  
Society of Public Health Education

Enclosure