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Docket No. 01P-0570

Submitted on Behalf of the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventive Medicine, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncologists, the American Thoracic Society, the Latino Council on Alcohol and Tobacco, the National Association of Local Boards of Health, the National Education Association, the Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and the Partnership for Prevention.

DECEMBER 18, 2001

01P-0570

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Citizen Petition

This is one of four petitions submitted to the Food and Drug Administration ("FDA") today by the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventive Medicine, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncologists, the American Thoracic Society, the Latino Council on Alcohol and Tobacco, the National Association of Local Boards of Health, the National Education Association, the Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and the Partnership for Prevention. The other petitions concern Ariva tobacco lozenges, OMNI and Advance "low carcinogen" cigarettes, and Nicotine Water. Each petition urges FDA to regulate a product that is being marketed to users of traditional tobacco products as a safer, healthier way of consuming tobacco or nicotine, or both.

Although the Supreme Court held last year that the FDA does not have jurisdiction over traditional tobacco products as customarily marketed, the Court left undisturbed the agency's jurisdiction over (1) nicotine-containing products other than traditional tobacco products and (2) traditional tobacco products that make drug claims. The manufacturer of Eclipse, which is the subject of this petition, has made explicit health claims about its product and has designed it explicitly to deliver nicotine. In addition, Eclipse bears no resemblance to a traditional tobacco product and is instead a mechanism carefully designed to deliver nicotine to consumers. Yet the manufacturer is marketing Eclipse with these claims without first submitting it to FDA for approval or without subjecting its product to government review. Instead, the manufacturer claims the product is exempt from government oversight because it has the same shape as a

cigarette and contains tobacco. As we demonstrate in this petition, Eclipse is in fact subject to various requirements of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as traditionally interpreted by the agency and the courts. Therefore, the FDA should grant this petition and prohibit the sale of Eclipse until the manufacturers have complied with the law.

Eclipse

The R.J. Reynolds Tobacco Company ("RJR") currently sells Eclipse in stores in four states and via direct mail through telephone and Internet sales in 38 states. Eclipse outwardly looks like a cigarette, but is in fact a sophisticated, technologically-advanced nicotine delivery system that is completely unlike traditional cigarettes. RJR claims that the structure and design of Eclipse enables users of that product to avoid the risks of developing diseases normally associated with smoking.

A. Action Requested

Petitioners request that the FDA require premarket approval of Eclipse under the FFDCA. Specifically, this petition requests that FDA classify, and therefore regulate, Eclipse as a "drug" within the meaning of the FFDCA, or, in the alternative, that FDA classify and regulate Eclipse as a medical device or combination drug/device under the FFDCA.[1]

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[1] On August 1, 2000, and March 15, 2001, the Center and 21 other groups by letter urged then-FDA Commissioner Henney and then-Acting Principal Deputy Commissioner Schwetz, respectively, to assert jurisdiction over and regulate Eclipse pursuant to the FFDCA. These letters are Attachments A and B to this Petition.

B. Statement of Grounds

RJR has used an extensive advertising campaign to tout Eclipse as a novel, reduced-risk tobacco product that is the "next best choice" to not smoking at all.[2] In particular, RJR has repeatedly represented that because of Eclipse's unique structure and design, users of that product are less likely than smokers of conventional cigarettes to develop serious diseases normally associated with smoking.

Eclipse is designed as a tobacco-heating nicotine delivery system that is different in important ways from conventional cigarettes. Instead of directly lighting shredded and dried tobacco leaves wrapped in tobacco paper, users of Eclipse light a carbon source at the tip of a hard casing. As the smoker sucks on an Eclipse, heat is passed through an aluminum tube past a layer of shredded tobacco paper and glycerin sandwiched between two insulating mats of glass fibers, creating a mist containing nicotine and other substances, which the smoker inhales. Unlike a cigarette, an Eclipse does not burn away as it is smoked, but rather stays largely intact with use.

The net effect of this design is that Eclipse burns only an incidental amount (three percent) of the tobacco burned by other cigarettes. RJR claims that, in contrast to conventional cigarettes, Eclipse:

- "may present less risk of cancer";
- "produces less inflammation in the respiratory system, which suggests a lower risk of chronic bronchitis and possibly even emphysema";
- "may pose less risk to smokers of developing cardiovascular disease";

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[2] *See* Eclipse print advertisement (Attachment C). *See also* "RJR To Test Reduced-Smoke Cigarette," *Associated Press*, April 19, 2000 (quoting RJR Chairman Andrew Schindler) (touting Eclipse as the "next best thing" to quitting smoking).

- "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"; and
- "responds to certain smoking-related illness, including cancer."[3]

These health claims are the focus of RJR's marketing strategy for Eclipse, and the company's public statements are laden with references to the "extensive scientific research" pointing to the relative benefits of Eclipse.[4] Descriptions of such evidence are included in the materials that accompany the product.[5]

RJR's health claims with respect to Eclipse bring that product within the FFDCA's definition of a drug, and subject the product to regulation by the FDA. The Agency has traditionally determined that products, including tobacco products, that are advertised as therapeutically beneficial must receive rigorous, independent Agency scrutiny in order to

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[3] *See* Attachment C. *See also* Marian Jones, "Less Deadly Cigarettes: Lesser Evil or Dangerous," *Fox News,* April 24, 2000; "Wake Forest Researchers Decry Use of Study to Back 'Eclipse' Health Claims," *Associated Press Newswires,* April 25, 2000 (quoting RJR Spokesman Seth Moskowitz).

[4] *See, e.g.*, "Groups Want FDA To Approve 'Eclipse'," *Associated Press*, August 19, 2000 (quoting RJR Spokesman Seth Moskowitz as saying that "[t]he claim that 'Eclipse' may present smokers with less risk of cancer, chronic bronchitis and possibly emphysema is fully supported by extensive scientific research"); "Wake Forest Researchers Decry Use of Study to Back 'Eclipse' Health Claims," *Associated Press*, April 25, 2000 (quoting Mr. Moskowitz as saying that RJR's "claims are based on the weight of the evidence of an extensive body of scientific research"); Marian Jones, "Less-Deadly Cigarettes: Lesser Evil or Dangerous Alternative," *Fox News*, April 24, 2000 (noting that RJR bases its health claims for Eclipse on "four-step scientific methodology" that reveals relative safety of that product).

[5] *See* "RJR To Test Reduced-Smoke Cigarettes," *Associated Press*, April 19, 2000 (noting that [t]he first carton [of Eclipse] a smoker purchases will include a brochure that describes how 'Eclipse' works, how it differs from regular cigarettes and information about the scientific test results"); "R.J. Reynolds to Expand 'Eclipse' Test to Texas," *Reuters*, January 2, 2001 (noting that "brochures will be available in the stores [selling Eclipse] to provide information about the scientific tests that were conducted on the cigarettes.")

determine whether the claims of beneficial effect are well-founded. RJR has made such health claims with respect to Eclipse, but these claims have not been verified or evaluated by the FDA or subject to the type of comprehensive, independent review that FDA would conduct for any other product. The need for this type of action is compelling in this case. The Institute of Medicine of the National Academy of Sciences, the Society for Research on Nicotine and Tobacco and other experts in the tobacco field that have reviewed the publicly available data on Eclipse have determined that there is insufficient evidence to support RJR's health claims for Eclipse.[6] It is the obligation of the FDA to ensure that RJR's claims, like the claims of any manufacturer purporting to sell a therapeutically beneficial product are subjected to an independent and thorough review by the Agency before the product becomes available nationwide.

As we demonstrate in Section 1, FDA should, consistent with its regulation of products making therapeutic health claims, classify Eclipse as a "drug" under the FFDCA. In this section, we further explain that even if RJR's claims regarding Eclipse do not qualify as "health claims," Eclipse still meets the definition of a "drug" under the FFDCA, and should be regulated as such. In section 2, we demonstrate that Eclipse also meets the statute's definition of a medical device and that of a combination drug/device, and falls under the FDA's jurisdiction for those reasons as well. In Section 3, we explain that the United States Supreme Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), does not prevent FDA from regulating Eclipse and other, similar products.

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[6] *See* Letter from John R. Hughes, Policy Committee Chair, Society for Research on Nicotine and Tobacco, to FDA Commissioner Henney "Re: Regulation of Eclipse" (June 16, 2000)

1. Eclipse is a "drug" within the FFDCA.

The FFDCA defines "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1)(B), 321(g)(1)(C). As discussed above, RJR has expressly represented in its promotional and marketing materials that Eclipse can mitigate or prevent diseases normally associated with smoking. Moreover, Eclipse is a nicotine-substitution product that is intended to deliver nicotine to the user in order to mitigate, or to temporarily treat, nicotine addiction. Finally, because it is a nicotine source, Eclipse is intended to affect the structure or function of the body. For each of these three reasons, Eclipse meets the FFDCA's definition of a "drug" and is subject to FDA regulation.

a. RJR's health claims regarding Eclipse demonstrate that that product is intended to mitigate or prevent diseases normally associated with smoking.

FDA's longstanding practice has been to treat as drugs products that claim, and are intended, to confer health benefits on consumers. Eclipse is such a product. As discussed above, RJR's promotional and marketing materials expressly suggest that Eclipse users are less likely than conventional cigarette smokers to develop diseases normally associated with smoking, including cancer, cardiovascular disease, chronic bronchitis and emphysema.[7]

(Attachment D); Institute of Medicine, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction" (February 22, 2001) (hereinafter *Clearing the Smoke*).

[7] FDA has long taken the position that the intended use of an article for purposes of the FFDCA can be determined by the claims made for it by the seller on the label or packaging, or in advertising or other promotional materials. *E.g., Action on Smoking and Health v. Harris,* 655 F.2d 236 (D.C. Cir. 1980). At the same time, as discussed *infra* at pp. 12-14, intended use *need not* be determined by such claims, but may also be determined by relevant objective evidence of foreseeable uses.

That Eclipse contains tobacco makes no difference. The Supreme Court's decision in *FDA v. Brown & Williamson* that FDA does not have jurisdiction in many instances to regulate tobacco products was limited to traditional products "as customarily marketed" and expressly recognized FDA's "well-established" jurisdiction over tobacco products that bear health-related claims. 529 U.S. at 133, 158; *see also Action on Smoking & Health v. Harris*, 655 F.2d at 239; *United States v. 46 Cartons,* 113 F. Supp. 336 (D.N.J. 1953); *United States v. 354 Bulk Cartons*, 178 F.Supp. 847 (D.N.J. 1959). And FDA has consistently asserted jurisdiction over tobacco products that, like Eclipse, were claimed as safer, healthier alternatives to conventional cigarettes.

For example, in the 1950's FDA asserted jurisdiction over Fairfax cigarettes on the grounds that the manufacturer claimed health benefits from use of the product, which was advertised as "a smoke that is actually better for your health than any other cigarette." *See* advertisement for Fairfax cigarettes (Attachment E). Some of the claims for Fairfax were similar to the claims for Eclipse – to wit, that the diseases associated with conventional cigarette smoking were less likely to afflict smokers of Fairfax-brand cigarettes:

> 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 [an ingredient of Fairfax cigarettes] increases the red blood cell count aroused curiosity as to what reaction the smoking of Fairfax cigarettes would have on the circulatory system. Several hundred people were tested on a U.M.A. thermocuple. The findings showed that 91 per cent of those tested disclosed no clinical evidence of any constriction.

Attachment E. FDA has since regularly reasserted its position regarding tobacco products bearing health claims, notably in 1972 and 1988, when the FDA Commissioner

testified before Congress that cigarettes claiming beneficial physical effects were be treated as drugs under the FFDCA.[8]

More recently, in 1992, the FDA addressed "Jazz" cigarettes, which were marketed as a nicotine-free "safe cigarette."[9] Like the Fairfax advertisements, the promotional materials for Jazz emphasized its potential health benefits, including statements indicating Jazz was less harmful than conventional cigarettes, such as: "Cigarettes Without Nicotine Means No Health Hazard . . . Now You Can Enjoy the Luxury of Smoking Without Worrying," and "This is the cigarette you have been waiting for! Smoke Jazz and Breathe . . . Easier."[10] Because the statements suggested that use of Jazz would prevent the onset of cancer associated with smoking conventional cigarettes, the FDA concluded it was "intended for use in the prevention of disease and/or to affect the structure or any function of the body," and issued a "Warning Letter" saying Jazz cigarettes were "drugs" under the FFDCA, requiring approval of a New Drug Application.[11]

Finally, in 1997, FDA addressed "GumSmoke," a tobacco-flavored chewing gum. Among the claims made for GumSmoke by its manufacturer, Star Scientific, Inc., was that the product would contain specially processed tobacco that was "TSNA-free."[12] FDA objected,

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[8] *See* Hearings on S. 1454 Before the Consumer Subcommittee, Senate Committee on Commerce, 92nd Cong. 240 (1972); Health Consequences of Smoking: Nicotine Addiction: Hearing Before the Subcommittee on Health and the Environment, House Committee on Energy and Commerce, 100th Cong. 17 (1988).

[9] Letter from Richard J. Chastonay, Director, Division of Drug Labeling Compliance, FDA, to Alan V. Phan, Harcourt Export Co. (September 30, 1992) (Attachment F)..

[10] Advertisement for Jazz Cigarettes (Attachment G); *see also Id.*

[11] Letter from Chastonay to Phan, *supra* n.9, at 2.

[12] Letter from Kevin M. Budich, Compliance Officer, Center for Drug Evaluation and Research, FDA, to Paul L. Perito, then-outside counsel for Star Scientific (July 22, 1998) (Attachment H). "TSNA" stands for "tobacco-specific nitrosamine," a known carcinogen.

concluding that the manufacturer's claims for GumSmoke could create the perception that it was a "milder, safer form of smokeless tobacco, or a milder, safer substitute for smoking conventional cigarettes."[13] FDA noted further that "any representations that the use of this product as an alternative to tobacco may prevent or mitigate diseases associated with tobacco use, would be regarded by the agency as 'drug' claims under section 201(g)(1) of the [FFDCA] and any such representations would cause this product to be a 'new drug' under section 201(p) of the Act."[14]

There can be no dispute that RJR, like the manufacturers of Fairfax Cigarettes, Jazz Cigarettes, and Gumsmoke, is claiming that Eclipse is a "safer substitute for smoking conventional cigarettes." Like those products, Eclipse is expressly intended "for use in the mitigation . . . or prevention" of diseases associated with smoking. 21 U.S.C. § 321(g). Thus, Eclipse falls within the FFDCA's definition of "drug," and is subject to regulation by the Agency.

RJR has taken the position that because the company is not asserting that use of Eclipse confers affirmative health benefits on users, but merely that it "may present smokers with less risk compared to" traditional cigarettes, it is not making any health claims regarding its product.[15] Put simply, RJR is claiming that there is a difference between "reduced-risk" claims

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[13] *Id.*

[14] *Id.*

[15] *See* Deirdre Davidson, "FDA Urged to Police 'Reduced Risk' Cigarettes," *Legal Times*, July 17, 2000 (hereinafter *Legal Times*) (quoting Seth Moskowitz) ("We are saying that the 'Eclipse' may present smokers with less risk compared to other cigarettes, so we are not saying the 'Eclipse' is a safe cigarette . . . .").

of the kind it is making with respect to Eclipse, and health claims over which FDA may exercise jurisdiction. The FDA has rejected this argument, and should do so again.

First, treating so-called reduced-risk tobacco products as "drugs" under the FFDCA is consistent with the statutory text because such products are intended to be used to mitigate or prevent diseases associated with smoking. As discussed in detail below, many, if not most, smokers are addicted to nicotine, and these smokers are the target audience for Eclipse. Reduced risk products like Eclipse are designed to furnish smokers who are addicted to nicotine with an alternative, "healthier" delivery system for that drug, and thereby to mitigate or prevent diseases associated with the traditional delivery system for nicotine – *i.e.*, cigarettes. The courts have held that the FFDCA's definition of drug should be liberally construed in order to effectuate the public health goals of the statute. *United States v. Article of Drug Bacto-Unidisk,* 394 U.S. 784, 792 (1969); *National Nutritional Foods Ass'n v. Weinberger,* 512 F.2d 688, 701-02 (2d Cir.), *cert. denied,* 423 U.S. 827 (1975). As set out above, regulation of tobacco products when they bear health claims was reserved as an appropriate exercise of FDA jurisdiction in the Supreme Court's *Brown & Williamson* decision. Treating reduced-risk products like Eclipse as drugs is therefore an entirely permissible construction of the FFDCA.

Second, the distinction drawn by RJR has already been rejected by the FDA itself, which, as discussed above, has regulated tobacco-related products on the grounds that those products were claimed to be safer than conventional cigarettes.

Third, RJR's distinction makes no sense as a matter of policy. Consumers are as likely to be misled by claims of relative safety as they are by claims of affirmative health benefits. This is especially true in the tobacco context, where smokers who are addicted to nicotine are looking for a relatively safe way to satisfy that addiction and are likely to rely on claims that a particular

tobacco product reduces the risks associated with smoking. RJR cannot dispute that its claims regarding Eclipse are designed to convince consumers of the relative health benefits of using Eclipse. FDA can, and should, regulate Eclipse on the basis of these claims.

b. Eclipse is intended temporarily to treat or to mitigate the disease of nicotine addiction.

Even if the claims made by RJR on behalf of Eclipse were not deemed health claims, Eclipse still meets the definition of a drug under the FFDCA because it is intended to treat or mitigate the disease of nicotine addiction.

It is widely recognized that nicotine addiction is a disease.[16] FDA has approved several products, including the nicotine patch, nicotine gum, and the nicotine inhaler, as drug treatments for nicotine addiction. Those products deliver nicotine to people who are addicted to that drug, but who do not want to smoke conventional cigarettes or use smokeless tobacco products.[17]

RJR's own statements about Eclipse confirm that the product is intended for those who are addicted to nicotine. Eclipse is being marketed as "the next best choice" to quitting smoking,[18] a strategy that assumes that prospective purchasers of the product will be smokers. The Company has also acknowledged that it is creating Eclipse in response to the demands of

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[16] World Health Organization, 3 *International Statistical Classification of Diseases and Related Health Problems* 537 (10th rev. 1994); American Psychiatric Ass'n, *DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders* 264-65 (4th ed., text rev. 2000); *see also* Office on Smoking and Health, Department of Health and Human Services, "The Health Consequences of Smoking: Nicotine Addiction, a Report of the Surgeon General" (1988) (hereinafter "Surgeon General's Report"), *available at* http://www.cdc.gov/tobacco/sgr_1988.htm.

[17] *See, e.g.*, *The Science of NRT (Nicotine Replacement Therapy)*, *available at* http://www.nicorette.com/nicr_internal/nrt4.html (last visited December 12, 2001) (Attachment I).

[18] *See* n.2, *supra*.

smokers who "want a cigarette with less risk."[19] And indeed, the promotional materials that accompany the product expressly alert smokers to adjustments they have to make when switching to Eclipse from conventional cigarettes.[20] It is clear, then, that RJR anticipates that the people who will buy the Eclipse device are primarily people who are addicted to nicotine. The product exists to provide an alternative source of nicotine for those who do not want to use conventional tobacco products. The very purpose of the product is to allow someone who is addicted to nicotine to avoid withdrawal symptoms. Eclipse is therefore functionally analogous to nicotine-substitution products, like nicotine gum, that were created to serve the same purpose and are regulated by the FDA as drugs.

Under the FFDCA, Eclipse may be "intended" as a nicotine-substitution product even if it has not been expressly marketed as such. The courts have made clear that under the FFDCA, FDA may ascertain actual intent on the basis of relevant objective evidence as well.[21] As the regulations implementing the FFDCA provide, "[t]he intent . . . may be shown by the circumstances surrounding the distribution of the article . . . [i]t may [also] be shown by the

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[19] "RJR To Test Reduced-Smoke Cigarette," *Associated Press*, April 19, 2000 (quoting David N. Iauco, RJR Senior Vice-President)("Smokers have consistently told us they want a cigarette with less risk, and 'Eclipse' may present less risk of certain smoking-related diseases.")

[20] *See, e.g.*, "R.J. Reynolds to Expand 'Eclipse' Test in Texas", *Reuters*, January 2, 2001 (When 'Eclipse' goes on sale at the Texas stores, Reynolds will sell[] three packs for the price of two, and the three packs will come with a brochure on how to make the transition to smoking 'Eclipse'").

[21] *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).

circumstances that the article is . . . being offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. §201.128.[22]

FDA has concluded that a manufacturer's intent under the FFDCA can be inferred when a reasonable person in the position of the manufacturer would foresee that the product will be used in a certain way (to treat or mitigate a disease) or will have certain effects (in this case, pharmacologic effects on the structure or function of the body).[23] That Eclipse will be used by consumers as a temporary treatment for, or to mitigate, nicotine addiction is clear. It is not only foreseeable to RJR; it is evident in the company's own statements about the product. Though RJR has so far failed to explicitly advertise Eclipse as a treatment for nicotine addiction similar to other nicotine substitution products, it is clear Eclipse is "intended" to treat or mitigate a disease for purposes of the FFDCA.

There are two apparent, but irrelevant, differences between Eclipse and other nicotine-substitution products. The first difference is that other such products are intended as, and marketed as, permanent solutions to nicotine addiction ("cessation aids"), while Eclipse is intended as a temporary, situation-specific treatment ("the next best choice" to quitting). The distinction is irrelevant given that under the FFDCA, a product that is intended for use in the *either* the treatment *or the mitigation* of a disease qualifies as a "drug." Cough syrup, for

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[22] Courts have held that evidence of consumer use is relevant in determining a product's "intended use." *National Nutritional Foods Ass'n v. Mathews*, 557 F.2d at 334 (FDA may determine intent from relevant objective evidence, including consumer use); *Action on Smoking & Health v. Harris*, 655 F.2d at 239-240 (consumer use can be relevant in determining manufacturer intent).

[23] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,690 (Aug. 28, 1996) (Final Rule). Although that regulation is no longer in effect since the Supreme Court's decision in *Brown & Williamson*, the FDA's analysis of "intended use" under the FFDCA, which was based on the

example, is a temporary treatment of the symptoms of a disease, but is no less a drug because it is not intended as a permanent cure. Eclipse was developed for the same disease as nicotine-substitution products, to achieve an analogous effect, and should be regulated as a drug.

The second apparent difference between Eclipse and other nicotine-substitution products is that the outside appearance of Eclipse actually resembles a conventional cigarette. RJR claims in fact that Eclipse *is* a cigarette, and that therefore, under the Supreme Court's *Brown & Williamson* decision, the FDA cannot regulate it.[24] RJR's claim is unfounded. Eclipse is a device that bears little resemblance to a cigarette. A cigarette is dried, shredded tobacco leaf rolled in paper that, when lit, burns the tobacco and produces smoke that is inhaled. *See Webster's Ninth New Collegiate Dictionary* 240 (1985) (defining a cigarette as "[a] slender roll of cut tobacco enclosed in paper and meant to be smoked.") The design and operation of an Eclipse differs from a conventional cigarette in many important respects. As discussed above, an Eclipse:

- Is wrapped in a hard casing, not wrapping paper;
- Is activated by lighting a carbon tip at the end of the casing, not by lighting and burning paper;
- Does not burn tobacco, but delivers nicotine by passing heat from the carbon tip through a three-quarter-inch aluminum tube to reach a chamber of shredded tobacco paper wedged between two fiberglass mats, thereby creating an inhalable mixture (not smoke) of nicotine, glycerol, and water; and

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Agency's historic application of that term to prescription and over-the-counter drugs, is still good law and was not addressed by the Supreme Court. 529 U.S. at 131-32.

[24] *See Legal Times*, *supra* n.15 (quoting Seth Moskowitz)("The fact of the matter is, the 'Eclipse' is a cigarette . . . . [FDA] tried to assert authority over the tobacco companies. The courts have upheld that the FDA has no regulatory authority over the tobacco industry.").

- Does not burn away as it is used, but rather remains intact, to be discarded after use.

In short, unlike a cigarette, an Eclipse is made of carbon, aluminum and fiberglass, not paper; is not burned; heats tobacco paper rather than burning tobacco leaf as the source of nicotine; does not produce smoke; and remains an intact shell after use. Eclipse is a sophisticated, technologically-advanced nicotine delivery system that does not resemble in any way the cigarette as we know it. Indeed, the principal similarity between traditional cigarettes and Eclipse is that both provide for the inhaling of nicotine through a tube-shaped design, a common characteristic that is also shared by the nicotine inhaler, which FDA recognizes and regulates as a drug delivery system.

The mere presence of shredded tobacco paper in the Eclipse is not enough to bring the product within the protection of the *Brown & Williamson* case. Nowhere in that case did the Supreme Court state that any product containing a tobacco derivative was outside the scope of FDA regulation. Rather, the Court's decision was limited to traditional tobacco products – *i.e.*, those products that Congress targeted when it chose to legislate in this area. 529 U.S. at 137-138. Eclipse clearly is not the kind of product that Congress had in mind when it acted in the area of traditional tobacco products. Rather, Eclipse is the functional equivalent of other nicotine-substitution products that are designed as alternatives to cigarettes and smokeless tobacco products and that are regulated by the FDA. The mere fact that the manufacturers include tobacco as an ingredient or component in these alternative products is of no moment. If, for example, a manufacturer of nicotine gum decided to use ground tobacco in its product as the nicotine source, that product would be no less a "drug" for purposes of the FFDCA. Failing to regulate Eclipse in the same way as other nicotine-substitution products would allow tobacco

companies to sell an equivalent product without any requirement that the product be found safe and effective by the FDA.[25]

c. Eclipse is intended to affect the structure or function of the body.

Even if Eclipse were not intended to treat nicotine addiction or to mitigate diseases normally associated with smoking, it would fall within the FFDCA's definition of "drug" because it is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C).

A 1988 Surgeon General's report documented the precise effects of nicotine on the body.[26] Stated generally, nicotine's actions on the structure or functions of the body include "electrocortical activation, skeletal muscle relaxation, and cardiovascular and endocrine effects."[27] Nicotine also acts upon receptors in nerve cells to create both nicotine tolerance and nicotine dependence.[28] It is clear, then, that Eclipse "affects the structure or function of the body."

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[25] The companies that market other nicotine substitution products, such as Nicorette nicotine gum and NicoDerm CQ nicotine patch have made precisely this point in urging FDA to exercise jurisdiction over such equivalent products as Eclipse. *See* Letter from Steve Burton, Head of Smoking Control, Strategic Development and Medical Promotion, SmithKline Beecham, to then-FDA Commissioner Henney (September 17, 2000) (Attachment J) (enclosures not included).

[26] "Surgeon General's Report", *supra* n.16, at 75-144.

[27] *Id.* at 14.

[28] Kolawole S. Okuyemi, Jasjit S. Ahluwalia, and Kari J. Harris, *Pharmacotherapy of Smoking Cessation*, 9 Archives Fam. Med. 270, 271 (2000) (Attachment K). More specifically, nicotine binds to "nicotinic acetylcholine receptors" in the nervous system, producing "enhanced alertness and mild euphoria." It also increases the number of these receptors, creating a need for more nicotine to maintain mood. *Id.*

As explained above, the great majority of users of tobacco products, the prospective market for Eclipse, are addicted to nicotine.[29] It is well documented that nicotine users, even if not addicted, seek the drug for its pharmacological effects, including relaxation, stimulation, and weight control.[30] A study of nicotine nasal spray showed how these effects, rather than any sensory effect associated with the products that contain nicotine, motivate people to consume the drug. In that study, users of nicotine spray showed characteristics of addiction, despite the unpleasant experience of using the spray itself, which has a highly unpleasant taste if allowed to run down the nasal passages into the throat, and irritates the nasal passages themselves, even causing ulcers in the nasal mucosa if overused.[31]

Eclipse is not a traditional tobacco product that simply delivers nicotine as a natural byproduct of its presence in the tobacco leaf. Eclipse is a highly engineered, sophisticated product in which the delivery of nicotine occurs as the result of careful calculation and intention in a manner that is entirely under the control of the manufacturer. Consumers will use Eclipse as a source of nicotine, a substance they seek precisely because of its effects on the structure or function of the body. As discussed above, RJR's own materials make clear the company intends that result. Eclipse should therefore be regulated as a drug under the FFDCA. There can be no question of the manufacturer's intent here.

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[29] 75-90% of frequent smokers and over one-third of smokeless tobacco users are addicted to nicotine. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314, 41487 (Aug. 11, 1995) (Proposed Rule) (synthesizing data on nicotine addiction).

[30] *See generally* "Surgeon General's Report", *supra* n. 16.

[31] 60 Fed. Reg. at 41,565 (citing FDA Drug Abuse Advisory Committee Background Information, Joint Abuse Liability Review of Nicotine Nasal Spray (Aug. 1, 1994)).

2. Eclipse is a Medical Device or Combination Drug/Device, Subject to Regulation by FDA.

The FFDCA defines a medical device as "an instrument, apparatus, implement, machine . . . or other similar . . . article" that achieves the same effects as a drug (*i.e.*, prevention/mitigation/treatment of disease, affecting structure/function of the body) without "chemical action within or on the body." 21 U.S.C. §§ 321(h)(2), (h)(3). Eclipse meets this definition and is therefore subject to FDA regulation even it is not treated as a drug under that statute.

RJR does not simply assert that Eclipse is a safer cigarette. Rather, as discussed above, the company claims to employ a specific, technologically-sophisticated mechanical process and design to deliver nicotine to the user, and thereby to insulate him or her from the harms normally associated with using conventional tobacco products. The company makes clear in its promotional materials that it is Eclipse's unique *design* that reduces the user's exposure to known carcinogens and produces a lower risk of disease. In short, Eclipse is "an instrument, apparatus, [or] implement" intended to mitigate or treat diseases normally associated with smoking without chemical action on the body. It meets the definition of a medical device under the FFDCA,[32] and is not a conventional cigarette.

Even if Eclipse does not qualify as a medical device under the FFDCA, it does qualify as a drug/device combination product that falls within FDA's jurisdiction under section 503(g) of the FFDCA. 21 U.S.C. § 353(g). As discussed above, Eclipse employs a sophisticated, engineered product to deliver a drug into a site in the human body. In this respect, Eclipse

[32] The courts have held that FFDCA's definition of "medical device", like the statute's definition of a "drug" should be liberally construed to effectuate the FFDCA's fundamental public health goals. *See United States v. an Undetermined Number of Unlabeled Cases*, 21 F.3d 1026, 1028 (10th Cir. 1994); *United States v. 23, More or Less, Articles*, 192 F.2d 308, 309 (2d Cir. 1951).

resembles the metered-dose nicotine inhaler, which FDA regulates as a combination product. Like the inhaler, Eclipse is an instrument that converts a drug – here, nicotine – into an aerosolized mist for inhalation and delivery to the lungs for absorption into the blood stream. And like the inhaler (but unlike a traditional cigarette), an Eclipse remains intact after use. Indeed, the similarities between the inhaler and an Eclipse are far greater than the similarities between an Eclipse and a traditional cigarette, and it is well within FDA's jurisdiction to regulate Eclipse, like the inhaler, as a combination product.

3. The Supreme Court in *Brown & Williamson* Preserved FDA's Authority to Regulate Products like Eclipse.

Whether FDA treats Eclipse as a drug or medical device, the Agency may assert jurisdiction over this product in order to evaluate RJR's claims that it is safer than traditional tobacco products.

The Supreme Court's *Brown & Williamson* decision does not indicate otherwise. In that case, the Court held that FDA does not have jurisdiction to regulate *conventional tobacco products as customarily marketed,* finding that Congress had not granted FDA authority over traditional tobacco products as customarily marketed. Among the reasons cited by the Court for the conclusion that Congress had not intended to grant FDA authority over traditional tobacco products was that Congress had enacted legislation concerning tobacco inconsistent with the Court's view that if FDA asserted jurisdiction over traditional tobacco products, the agency would be required to ban the sale of those products. 529 U.S. at 137. The Court clearly concluded that Congress had not intended to ban traditional tobacco products as customarily marketed even if they were dangerous, but the exemption carved out for the traditional tobacco products as customarily marketed does not apply more broadly and does not apply to Eclipse.

Brown & Williamson does not prevent FDA from regulating Eclipse, for three reasons. First, as discussed above, the Court's holding did not affect FDA's longstanding authority to regulate as drugs tobacco products bearing health claims. Rather, in the *Brown & Williamson* case, the Court concluded that Congress had effectively ratified FDA's prior interpretation of its own authority, 529 U.S. at 158-59, which historically included, and continues to include, FDA regulation of tobacco products bearing health claims. As outlined above, RJR has made explicit and implicit health claims about Eclipse that bring it within FDA's jurisdiction and outside the scope of *Brown & Williamson.*

Second, the Court's opinion focused on FDA's 1996 jurisdictional statement, in which the Agency reversed its longstanding position that it should not regulate *traditional cigarettes and smokeless tobacco products as customarily marketed.* 529 U.S. at 125 (citing 61 Fed.Reg. 44,619 - 45,318). As explained above, Eclipse is not a traditional tobacco product, and in fact has more in common with nicotine substitution products under FDA jurisdiction than with conventional cigarettes. Given the significant harm caused by traditional tobacco products, the exemption from FDA jurisdiction recognized by the Supreme Court in *Brown & Williamson* should be construed narrowly in order to protect the public health. There is no evidence that Congress intended to exempt a broad range of products that do not bear the characteristics of traditional tobacco products then on the market.

Third, central to the Court's holding in *Brown & Williamson* was its finding that FDA regulation of the tobacco products at issue would necessarily lead to a ban on conventional tobacco products as customarily marketed, which would contradict the Court's conclusion that Congress did not intend to ban these products. Granting this petition will not result in a ban on conventional tobacco products. Rather, it will simply place on RJR the burden of demonstrating

that the health claims the company has made for Eclipse are accurate and that the product can comply with the agency's safety standards. Thus, FDA regulation of Eclipse is not inconsistent with the Court's interpretation of Congress' intent, and continues to be within the Agency's authority.

* * *

At the present time, there is no evidence before FDA to demonstrate that Eclipse is a safe product. Indeed, it has been suggested that the health claims relating to Eclipse are, in fact, false, and that the novel technological features of Eclipse actually create new dangers for consumers.[33] The issue is not whether Eclipse may or may not ultimately be found to be less hazardous than traditional tobacco products; it is whether this product and the claims made about it are going to be subject to government scrutiny before it is widely marketed to an unprotected public. Clearly, *the product must be subjected to Agency scrutiny before any conclusions are drawn as to the product's safety, and before Eclipse becomes widely available in the market.*

This approach is consistent with Agency practice regarding other substitutes for conventional tobacco products. FDA has regulated the nicotine patch, nicotine gum, and the nicotine inhaler. That Eclipse resembles a cigarette and is made by a tobacco company does not compel a different result. Indeed, for FDA to decline to regulate Eclipse would be to create an

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[33] *See, e.g.,* Attachment D; *Clearing the Smoke*, *supra* n.6; Frank Phillips, "'Non-Burning Cigarette No Healthier, Study Says," *Boston Globe*, October 4, 2000 (citing Massachusetts Department of Public Health study finding that Eclipse contains a higher percentage of certain cancer-causing agents than certain ultralight cigarettes currently on the market). And even if users of Eclipse run less risk of incurring diseases associated with smoking cigarettes, Eclipse may pose new health problems for users, such as inhalation of fiberglass particles. *See,* Pauly JL, et al., "Glass Fiber Contamination of Cigarette Filters: an Additional Health Risk to the Smoker?" *Cancer Epidemiol Biomarkers Prev.* 1998; 7:967-979 (Attachment L) (demonstrating that users of Eclipse ran the risk of inhaling glass fibers that were broken off the product's insulating mats during manufacturing).

immense regulatory void and a profit incentive for tobacco companies to market their product in novel forms intended for human consumption, but with an uncertain level of safety.

RJR is not alone in developing alternative tobacco products that employ new technologies and designs and are of uncertain safety. Philip Morris Co. is in the process of developing Accord, which, like Eclipse, uses a mechanical device to heat, rather than burn, tobacco. Other companies are developing cigarettes that purportedly contain reduced amounts of nitrosamines. Many of these products are being, or are expected to be, marketed as safer than conventional tobacco products. But it is unclear not only whether these products reduce the risks associated with using conventional tobacco products, but also whether the products introduce *new* risks to consumers by virtue of their novel designs and technologies. The development and marketing of these nontraditional tobacco and nicotine products make it essential that FDA assert its jurisdiction to prevent the public from being subjected to wholly unregulated claims and untested products with no protection whatsoever.

C. Conclusion

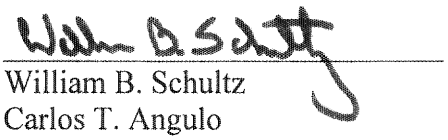
For the foregoing reasons, FDA should assert jurisdiction over Eclipse, classify Eclipse as a "new drug" that cannot be marketed without FDA approval, and invite RJR to submit a "new drug" application for the product. In the alternative, FDA should classify Eclipse as a Class III medical device or as a combination drug/device, and should invite RJR to seek premarket approval of Eclipse pursuant to Agency rules governing such products.

D. Environmental Impact

This petition qualifies for categorical exclusion under 21 C.F.R. §§ 25.15, 25.30-25.32, and therefore does not require the preparation of an environmental assessment or an

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 petitioners which are unfavorable to the petition.



William B. Schultz
Carlos T. Angulo
Meredith E. Cabe
Zuckerman Spaeder LLP
1201 Connecticut Avenue, NW
Washington, DC 20036
(202) 778-1800

Matthew Myers
William Corr
National Center for Tobacco-Free Kids, Inc.
1400 Eye Street, N.W., Suite 1200
Washington, DC 20005
202-296-546

Attorneys for the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventive Medicine, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the American Society of Addiction Medicine, the American Society of Clinical Oncologists, the American Public Health Association the American Thoracic Society, the Latino Council on Alcohol and Tobacco, the National Association of Local Boards of Health, the National Education Association, the Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and the Partnership for Prevention.

Dated: December 18, 2001