

**BEFORE THE U.S. FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ROCKVILLE, MARYLAND**

)	
Petition for Regulation of)	
R.J. Reynolds' "Eclipse" Product.)	
)	Dkt. No. 01P-0570/CP 1
Petition of the National Center)	
for Tobacco-Free Kids, <i>et al.</i>)	
)	

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**COMMENTS OF R.J. REYNOLDS TOBACCO COMPANY
ON THE "PETITION FOR REGULATION OF
R.J. REYNOLDS' 'ECLIPSE' PRODUCT" SUBMITTED BY
THE NATIONAL CENTER FOR TOBACCO-FREE KIDS et al.**

Pursuant to 21 C.F.R. § 10.30(d) (2001), R.J. Reynolds Tobacco Company ("Reynolds") submits the following comments on the Citizen Petition entitled "Petition for Regulation of R.J. Reynolds' 'Eclipse' Product" ("Petition") submitted on December 18, 2001 by the National Center for Tobacco-Free Kids et al. For the reasons discussed below, the Petition should be denied.

I. NATURE OF THE PETITION.

The Petition relates to Eclipse, a cigarette that primarily heats the tobacco it contains, but also burns some of that tobacco. Like other cigarettes, Eclipse contains tobacco and produces smoke that smokers inhale and exhale. The end of an Eclipse cigarette, however, also contains a heat source made primarily of high purity carbon. When a smoker lights the heat source and draws on an Eclipse cigarette, warm air passes through the tobacco, thereby heating the tobacco to vaporize glycerin and release the natural flavors of the tobacco. Because it burns far less tobacco as compared to other cigarettes, Eclipse produces, among other

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things, dramatically lower concentrations of many known, probable, and possible carcinogenic smoke compounds.¹

Petitioners ask FDA to assert jurisdiction over Eclipse under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301-397 (2000), on the grounds that: (a) Reynolds allegedly makes “health claims” in the promotional and marketing materials for Eclipse (Petition, at 6-11); (b) Eclipse allegedly is intended “temporarily to treat or mitigate the disease of nicotine addiction” (*id.* at 11-16); (c) Eclipse is intended to affect the structure or function of the body (*id.* at 16-17); (d) rather than being a cigarette that contains tobacco, Eclipse allegedly is a “medical device” or “drug/device combination” that converts nicotine into an aerosolized mist for inhalation and delivery to the lungs (*id.* at 18-19); and (e) Eclipse, by virtue of its structure and functional characteristics, falls outside the regulatory “exemption” recognized by the Supreme Court in FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) (“Brown & Williamson”), which extends, according to petitioners, only to “*traditional tobacco cigarettes and smokeless tobacco products as customarily marketed*” (Petition, at 20 (emphasis in original)). Under any of these theories, petitioners ask FDA to require Reynolds to obtain FDA approval before marketing Eclipse for sale to consumers. *Id.* at 22.²

¹ See Exhibit A (product brochure entitled “The Science Behind Eclipse”), at p. 3; see also R. J. Reynolds Tobacco Co., Eclipse: A Cigarette that Primarily Heats, Rather than Burns, Tobacco – Summary of Scientific Tests, at p. 16 (April 2000) (attached as Exhibit B).

² Each of these issues has been raised by petitioners in previous submissions to FDA. Reynolds’s responses, which address certain aspects of these issues at greater length, are incorporated herein by this reference. See, e.g.,

As is discussed below, Reynolds's response to the Petition is fourfold. First, the promotional materials for Eclipse do not justify classifying Eclipse as a drug or device because the claims identified by petitioners are not therapeutic in nature, i.e., are not of the type that falls within FDA jurisdiction. Second, the differences between Eclipse and other cigarettes are not material in determining whether it is a "cigarette" pursuant to the tobacco-specific legislation addressed in Brown & Williamson. Third, the labeling issues raised by the Petition are appropriately addressed by the Federal Trade Commission rather than FDA. Fourth, classifying Eclipse as a drug and/or device would be contrary to sound public policy.

II. ECLIPSE CANNOT BE CLASSIFIED AS A DRUG BECAUSE ITS PROMOTIONAL MATERIALS DO NOT MAKE THERAPEUTIC CLAIMS.

The principal argument of the Petition is that FDA should exercise jurisdiction over Eclipse because marketing materials for Eclipse make what petitioners broadly term "health claims." See, e.g., Petition, at 3-5. This argument

Continued ...

Comments of R.J. Reynolds Tobacco Company (Dkt. Nos. 88P-0155/CP, 88P-0155/CP0002) (Aug. 23, 1988); Comments of R.J. Reynolds Tobacco Company on the "'Smokeless Cigarette' or 'Smokefree Cigarette'" Citizen Petition Submitted By Action on Smoking and Health (Dkt. Nos. 94P-0069/CP1, 94P-0077/CP2 and 94P-0456/CP1) (Feb. 8, 1995); Letter from Richard M. Cooper to Dockets Management Branch (Dkt. No. 94P-0456) (May 24, 1996); Letter from Richard M. Cooper to Judith Wilkenfield, Esq. (June 19, 1996); Letter from Richard M. Cooper to Dockets Management Branch (Dkt. No. 94P-0456) (July 30, 1996); Letters from Robert L. Suber to Mitchell Zeller (March 16, 2000 and April 12, 2000); Letter from Paul K. Dueffert to Dr. Bernard Schwetz (February 2, 2001).

both misconstrues the standard under which FDA may assert jurisdiction and misrepresents the nature of the advertising for Eclipse.

To regulate Eclipse, it must be shown that Reynolds intends to promote Eclipse “for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” or “to affect the structure or any function of the body.” See FDCA § 201(g)(1)(B), (g)(1)(C), (h)(2), (h)(3), 21 U.S.C. § 321(g)(1)(B), (g)(1)(C), (h)(2), (h)(3).

Regulations promulgated pursuant to this standard establish that claims of reduced risk – as opposed to therapeutic effect – are not a valid basis for classifying a product as a drug or a device. In a variety of contexts, FDA has consistently recognized that claims and representations that a product will not cause a particular kind of adverse effect, or presents less risk of an adverse effect, or does not contain (or contains a lesser amount of) a substance or compound associated with an adverse effect, do not make the product a drug or a device.

Thus, for example, without becoming a drug or a device:

- a food may claim to be hypoallergenic, 21 C.F.R. § 105.62 (2001);
- a food may claim to be low in calories or to contain reduced calories, 21 C.F.R. §§ 101.60(b), 105.66 (2001);
- a food may be labeled “sodium free” or “low sodium” or “very low sodium” or “reduced sodium,” 21 C.F.R. §§ 101.13, 101.61(b) (2001); and a food may claim to be useful as a means of regulating the intake of sodium, 21 C.F.R. § 105.66 (2001); and

- in certain circumstances, a food may be labeled “sugar free,” “sugarless,” etc., and may claim that it does not promote dental cavities. 21 C.F.R. §§ 101.80(c)(2)(C), (D); 105.66(f) (2001).

In the same way, the claims made for Eclipse are not claims of positive therapeutic benefit or beneficial effect on the body or any of its functions. All of the claims identified in the Petition convey only that Eclipse is or may be less risky in certain respects than other cigarettes. See Petition, at 3-4 & Exhibit C (reflecting claims, for example, that Eclipse “may present less risk of cancer” and “produces less inflammation in the respiratory system, which suggests a lower risk of chronic bronchitis, and possibly even emphysema” (emphasis added)).³ There is no claim that Eclipse may be useful in the diagnosis, cure, mitigation, treatment, or prevention of any exogenous disease, process, or state. Nor is there any claim that Eclipse is intended to affect the structure or any function of the body.

Deputy Commissioner Mark Novitch explained the rationale for exempting such claims from FDA’s drug and device jurisdiction in a speech in 1984:

Current FDA rules prohibit any labeling that makes health claims. But we have allowed labeling such as ‘no preservatives,’ ‘no artificial flavoring,’ ‘no artificial coloring,’ or ‘no caffeine’ – which connote that people ought to avoid these things. We have not moved against those kinds of claims because

³ The advertisement attached to the Petition as Exhibit C was used between April 2000 and December 2000. More recent promotional materials for Eclipse are attached as Exhibit A (product brochure delivered to health care providers in the Dallas-Fort Worth area in January 2002) and Exhibit C (handout currently distributed through retailers in Dallas-Fort Worth area).

they are truthful and they do not make outright health claims.⁴

Commissioner Frank Young accepted this distinction when, in congressional testimony in 1987, he approved the jurisdictional distinction between “avoidance” claims and “prevention” claims.⁵

Indeed, the distinction between therapeutic claims and reduced-risk claims is illustrated in the 1950s-era cigarette cases cited at pages 7-8 of the Petition. In United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953), FDA contended that the labeling of the Fairfax cigarettes at issue represented them as effective in preventing the

common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis (parrot fever).

⁴ Quoted in Peter Barton Hutt, Government Regulation of Health Claims in Food Labeling and Advertising, 41 Food Drug Cosmetic L.J. 3, 47 (1986). Petitioners’ contrary assertion that FDA “has regulated tobacco-related products on the grounds that those products were claimed to be safer than conventional cigarettes” is both incorrect and unsupported by citation to any judicial or other authority. See Petition, at 10.

⁵ FDA Proposals To Permit the Use of Disease-Specific Health Claims on Food Labels: Hearing Before a Subcomm. of the House Comm. on Gov. Operations, 100th Cong. 5-6 (1987) (statement of Frank E. Young, M.D., Commissioner, Food and Drugs) (quoting Richard M. Cooper, Health Claims on Foods – Reflections on the Food/Drug Distinction and on the Law of Misbranding, 44 Am. J. Clinical Nutrition 560 (1986)). The distinction also is reflected in the case law. See, e.g., FTC v. Pharmtech Research, Inc., 576 F. Supp. 294, 297 (D.D.C. 1983); FTC v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 575 (S.D.N.Y. 1952), aff’d on op. below, 203 F.2d 955 (2d Cir. 1953).

113 F. Supp. at 337. In determining whether such claims constituted a basis for FDA jurisdiction, the court framed the appropriate question as being

whether the public, having in mind the specious statements of the leaflets, would buy Fairfax cigarettes primarily for smoking enjoyment or with the hope of mitigating, curing or preventing disease.

. . . .

If claimant's labeling was such that it created in the mind of the public the idea that these cigarettes could be used for the mitigation or prevention of the various named diseases, claimant cannot now be heard to say that it is selling only cigarettes and not drugs.

113 F. Supp. at 338. Thus, a product marketed "primarily for smoking enjoyment" would not be a drug or device, whereas a product with therapeutic claims would be. In view of the extreme claims made for Fairfax cigarettes, the court had no trouble finding that the product was a drug. Id. at 339.

Similarly, United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959), involved cigarettes to which tartaric acid had been added and which were represented as useful in a weight-reduction program. The manufacturer made it clear, in its labeling, that the product was not being marketed for smoking taste and pleasure. Rather, in the words of the court, the labeling informed prospective purchasers "that these reducing aid cigarettes are not intended to replace the purchaser's favorite cigarettes nor to change his present smoking habits." Id. at 849. In view of the manufacturer's admitted claims and representations, the court easily determined that the product was a drug.

Nothing in the reasoning of these cases is limited to cigarettes as distinct from cigars, pipes, and other tobacco products offered for smoking taste and pleasure. Nor do these decisions create any peculiar or anomalous exception from the FDCA for cigarettes. Rather, the decisions apply to the products at issue the well-settled interpretations of FDCA § 201(g)(1)(B)-(C), (h)(2)-(3), 21 U.S.C. § 321(g)(1)(B)-(C), (h)(2)-(3): namely, (i) that in order for a product to be a drug or device its manufacturer or vendor must represent it as having a therapeutic use or as affecting the structure or function of the body in a therapeutic or quasi-therapeutic manner; (ii) that a representation that a product – any product – is to be used for smoking taste and pleasure is not the kind of representation that brings it within § 201(g)(1)(B) or (C), or (h)(2) or (3); (iii) that a claim of lack of, or less frequent or less severe, adverse effects is not a drug or device claim; and (iv) that a product's actual characteristics or actual or assumed adverse effects do not make it a drug or device. See Comments of R.J. Reynolds Tobacco Company, FDA Dkt. Nos. 88P-0155/CP, 88P-0155/CP0002, at 70-72 (Aug. 23, 1988).

Judged by this standard, the promotional materials for Eclipse do not support an assertion of jurisdiction by FDA. The cover of the current consumer brochure for Eclipse states:

MAY PRESENT
LESS RISK
LESS ODOR
eclipse
A BETTER WAY TO SMOKE

Exhibit C, at 1. The second page carries the following headline:

**THE BEST CHOICE FOR SMOKERS
WORRIED ABOUT THEIR HEALTH IS TO QUIT.**

THE NEXT BEST CHOICE IS TO SWITCH TO ECLIPSE.

Id. at 2.

The brochure proceeds to identify the potential consumers of Eclipse and the respects in which the product may present reduced health risks as compared to other cigarettes:

Eclipse is not a cigarette for people who want to avoid the risks of smoking. No cigarette is without risk. And it's not for smokers who want to quit.

Eclipse is for smokers who have decided not to quit, but who are interested in a cigarette that responds to concerns about certain smoking-related illnesses, including cancer. For those who choose to smoke, it is a better way.

ECLIPSE AND YOUR HEALTH.

Scientific studies show that compared to other cigarettes, **Eclipse may present less risk of cancer, chronic bronchitis and possibly emphysema.**

Id. (emphasis in original).

The brochure then addresses, among other things, the manner in which Eclipse provides smoking pleasure to consumers. It explains that “[a]s you draw, the heated air passes through choice tobaccos releasing flavors (including nicotine) and other components to produce smoke that you inhale and exhale.” Id. The brochure also discusses differences between Eclipse and other cigarettes,

including functional differences (e.g., “Eclipse primarily heats rather than burns tobacco”), differences in smoke components (e.g., 75% less tar and nicotine), and differences in the ways consumers use the product (e.g., “keep the flame burning at the tip while you take three or four long, easy puffs”). See id. at 2-4. Finally, the last page of the handout emphasizes that the product does not address all of the risks of smoking. See id. at 4 (e.g., “We don’t claim that Eclipse presents less risk of cardiovascular disease or complications with pregnancy”).

Thus, unlike the manufacturers of the products at issue in the cases relied upon by petitioners, Reynolds markets Eclipse for smoking pleasure, and makes no claim that Eclipse is useful in the diagnosis, cure, mitigation, treatment, or prevention of any exogenous disease, process, or state. See also Exhibit A (product brochure distributed to health care providers); Petition Exhibit C (Eclipse advertisement discussed by Petitioners).

Disregarding the claims actually made by Reynolds in its promotional materials for Eclipse, petitioners argue that Eclipse is, in actuality, intended to serve as a “temporary, situation-specific treatment” for the “disease” of “nicotine addiction.” Petition, at 1-2, 6, 10, 12-13, 15, 17-19. This argument is plainly wrong. A substance whose consumption causes and perpetuates an addiction cannot properly be viewed as a “drug” or a “device.” Feeding an addiction is not the same as mitigating, curing, or otherwise treating it; and no addicting agent is recognized

as a treatment for the addiction it causes.⁶ For example, alcohol is not a “drug” for the “mitigation” or “treatment” of alcoholism. Similarly, a slot machine is not a medical device for treating addiction to gambling.

In the same way, a tobacco product is not a treatment for addiction to nicotine. Indeed, if petitioners’ argument were valid, it would apply equally to extend FDA jurisdiction to conventional cigarettes (as well as alcohol and other products with addictive qualities), which is contrary to the holding of Brown & Williamson.

Here, moreover, Reynolds makes no claim that Eclipse is useful in the treatment of any addiction, nor does Reynolds claim that Eclipse is useful in achieving any reduction in, or elimination of, withdrawal symptoms. See Exhibits A and C; Petition Exhibit C. In asking FDA nonetheless to assert jurisdiction over the product, petitioners claim that a manufacturer’s “intended use” should be inferred from all of the reasonably foreseeable uses of a product. See Petition, at 12-13.

To support that argument, petitioners cite only to FDA commentary accompanying the 1996 tobacco regulations that later were struck down by the Supreme Court in Brown & Williamson. Id. at 13 n.23 (citing 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))

⁶ It is true that drugs such as morphine have addictive properties. These drugs do not fall within the FDA definition of “drug” because they are addictive, however, but because, in view of their other pharmacological properties, they are marketed with representations that they have a medical purpose (e.g., analgesia).

(Final Rule)). Far from being “based on the Agency’s historic[al] application of that term,” see id., the interpretation of “intended use” articulated by FDA in its unsuccessful effort to assert jurisdiction over cigarette products was inconsistent with prior administrative and judicial interpretations of that term.

Congress in 1938 articulated a special meaning for “intended use”:

The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S. Rep. No. 361, 74th Cong. 4 (1935) (emphasis added). Courts and (with the exception of the 1996 tobacco rulemaking cited by petitioners) FDA have treated this passage as authoritative. See Action on Smoking & Health v. Harris, 655 F.2d 236, 238-39 (D.C. Cir. 1980); United States v. An Article Consisting of 216 Individually Cartoned Bottles, 409 F.2d 734, 739 n.3 (2d Cir. 1969); United States v. 23, More or Less, Articles, 192 F.2d 308, 309 (2d Cir. 1951); 56 Fed. Reg. 60,537, 60,546 (1991). Indeed, even a manufacturer’s undistributed promotional materials with therapeutic claims do not establish an intended use because they have not been communicated in the market. United States v. Articles of Drug for Veterinary Use, 50 F.3d 497, 500-01 (8th Cir. 1995).

Not only would petitioners’ interpretation of “intended use” overturn decades of settled judicial authority and agency practice, but the acceptance of petitioners’ position also would have dramatic and plainly unacceptable consequences. For example, many drugs have medically important off-label uses

that are widespread, foreseeable, and known to manufacturers. See FDA, Use of Approved Drugs for Unlabeled Indications, FDA Drug Bulletin, Apr. 1982, at 3 (“accepted medical practice often included drug use that is not reflected in approved drug labeling”). FDA has not treated off-label use as an intended use where the manufacturer or other vendor did not claim the use in connection with sale. Accepting petitioners’ position as to the meaning of “intended use” would require FDA to treat many off-label uses as intended uses. Such treatment would render drugs with such uses unlawful because they would lack approval, and their labeling would lack adequate directions, for all “intended uses.”

Another unacceptable consequence of petitioners’ interpretation of “intended use” would be the creation of anomalies in other statutes. For example, the Consumer Product Safety Act (“CPSA”) exempts from the term “consumer product” “drugs” and “devices” “as such terms are defined in . . . the [FDCA].” 15 U.S.C. § 2052(a)(1)(H) (2000). If every consumer product that foreseeably affects the structure or function of the body is a “drug” or a “device,” then every such product is excluded from the jurisdiction of the CPSA – whether or not FDA actually regulates it. There are many such products, including, for example, space heaters, electric hair curlers, and playground equipment.

The presence of nicotine in Eclipse thus is irrelevant to the question of FDA jurisdiction so long as Reynolds does not claim a therapeutic role for Eclipse. Reynolds, like the vitamin manufacturers in Mathews, does not represent its product to be effective in the cure, mitigation, treatment, or prevention of any

disease. The presence of nicotine in Eclipse, accordingly, is irrelevant as a matter of law. See Mathews, 557 F.2d at 335.

As noted above, if petitioners were correct in contending that Eclipse is subject to FDA regulation because it “mitigates” the disease of “nicotine addiction,” all cigarettes would fall under FDA’s jurisdiction and Brown & Williamson would have been decided otherwise. Their argument in this regard thus is contrary to law.⁷

III. FDA JURISDICTION IS NOT ESTABLISHED BY ECLIPSE’S STRUCTURE OR FUNCTIONAL CHARACTERISTICS.

Petitioners assert that FDA should exercise jurisdiction over Eclipse on the basis that it not a “conventional cigarette” or “traditional tobacco product” and therefore is outside the “exemption” to FDA jurisdiction recognized by the Supreme Court in Brown & Williamson. See Petition, at 14-15, 19-21. In making this argument, petitioners describe a number of structural and functional characteristics

⁷ Petitioners cite United States v. Article of Drug Bacto-Unidisk, 394 U.S. 784, 792 (1969), for the proposition that “the FDCA’s definition of drug should be liberally construed in order to effectuate the public health goals of the statute.” Petition, at 10. As the Supreme Court held almost two decades later, however:

[N]o legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice – and it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute’s primary objective must be the law.

Rodriguez v. United States, 480 U.S. 522, 525-26 (1987) (emphasis in original). In ruling on the Petition, FDA must interpret the legislative choice reflected in the FDCA in light of the legislative choices embodied in tobacco-specific legislation such as the Federal Cigarette Labeling and Advertising Act (“FCAA”), 15 U.S.C. §§ 1331-1341 (2000).

of Eclipse and, to some extent, mischaracterize the product. Regardless of how Eclipse is characterized, however, the differences between Eclipse and other tobacco products do not exclude Eclipse from the scope of the tobacco-specific statutes relied on by the Court in Brown & Williamson.

A. Eclipse Is a Cigarette Subject to the Tobacco-Specific Legislation.

In Brown & Williamson, the Supreme Court held that the FDCA does not vest the FDA with jurisdiction to regulate tobacco products as “drugs” or “drug delivery devices” because, *inter alia*, Congress has established a distinct framework of “tobacco-specific legislation” to regulate “tobacco products” (including but not limited to “cigarettes and smokeless tobacco”). 529 U.S. at 154-59. The Court did not limit its holding to what petitioners term “traditional tobacco products.” Rather, it held that FDA has no jurisdiction over a range of tobacco products (for which no therapeutic claims are made) that collectively are subject to a panoply of tobacco-specific statutes outside the FDCA. *Id.* at 142-57.

In enacting this tobacco-specific legislation, Congress has set forth a specific statutory test as to what constitutes a “cigarette.” The term is defined in § 3 of the Federal Cigarette Labeling and Advertising Act (“FCLAA”) as follows:

As used in this chapter –

- (1) The term “cigarette” means –
 - (A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and
 - (B) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler,

or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (A).

15 U.S.C. § 1332 (2000). Identical definitions appear in 26 U.S.C. § 5702(b) (1994) (Internal Revenue Code) and in 18 U.S.C. § 2341(2) (2000) (trafficking in contraband cigarettes).

Petitioners entirely ignore these federal statutory definitions and assert that the Brown & Williamson decision pertained only to “traditional cigarettes.” Petition, at 14-15, 19-21. That term nowhere appears in the statutory definitions, however, and Brown & Williamson is nowhere so limited. The Court’s holding and rationale apply equally to any product that fits the governing statutory definition of “cigarette” set forth above.

As a factual matter, moreover, nothing in the Petition warrants a conclusion that Eclipse falls outside the scope of these statutes by failing to meet the statutory definition of “cigarette” – i.e., a “roll of tobacco wrapped in paper or in any substance not containing tobacco.” Eclipse plainly satisfies this definition – it is a “roll of tobacco” that is “wrapped in paper” and other substances not containing tobacco. In particular, it is wrapped in a conventional cigarette papers as well as laminates of cigarette paper and food-grade aluminum foil. See Exhibit B, at 3-4.

Indeed, Eclipse contains tobacco in three places: two forms of reconstituted tobacco sheet in its rod, tobacco paper between the insulating layers around the heat source, and ground tobacco in the heat source. Id. As the ordinary language used to identify these forms of tobacco makes clear, they are all forms of

tobacco.⁸ Moreover, the amount of tobacco in an Eclipse cigarette (about 500 mg) is comparable to the amount of tobacco contained in many other cigarettes.

⁸ A number of agencies that have long experience and expertise in determining what articles are cigarettes, and in regulating cigarettes, have recognized that reconstituted tobacco is a form of tobacco. For example, Chapter 24 of the U.S. International Trade Commission's Harmonized Tariff Schedule of the United States (2002 ed.) is entitled "Tobacco and Manufactured Tobacco Substitutes." Within this chapter, part 2403 is entitled "Other Manufactured Tobacco and Manufactured Tobacco Substitutes; 'Homogenised' or 'Reconstituted' Tobacco; Tobacco Extracts and Essences." The organization of part 24.03 is as follows:

2403.10 – Smoking tobacco, whether or not containing tobacco substitutes in any proportion

– Other:

2403.91 – "Homogenised" or "reconstituted" tobacco

2403.99 – Other

Tobacco substitutes are included under 2403.10. Reconstituted tobacco is included under a different provision, 2403.91. The U.S. Customs Service thus recognizes that reconstituted tobacco is manufactured tobacco.

Similarly, under the U.S. Patent Classification System, "tobacco" is defined to include products "containing tobacco or tobacco substitutes intended for personal use for smoking or chewing or for use as snuff." U.S. Patent and Trademark Office, U.S. Patent Classification System – Classification Definitions as of June 30, 2000, Class 131 (Tobacco), available at <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/def/131.htm>. The definition further notes that, "The word 'tobacco', as used in this class, is considered generic to any material which may be smoked or may be substituted for real tobacco." Id.; see also id., subclass 347 (encompassing component parts of tobacco products), subclass 353 (encompassing "sheet, strip, or leaflike products formed from a combination of two or more pieces of tobacco in any form"), subclass 357 (encompassing tobacco sheet from wet ground or wet beaten tobacco), subclass 358 (encompassing reconstituted tobacco used as a wrapper), and subclass 359 (encompassing tobacco substitutes). Thus, the PTO distinguishes between tobacco substitutes and reconstituted tobacco, and regards the latter as tobacco. It is beyond dispute that Eclipse falls within the PTO's defined classification for a tobacco product.

Apart from containing tobacco, Eclipse and other cigarettes share a host of characteristics. The length and diameter of Eclipse are comparable to those of other cigarettes. Eclipse also looks like any other cigarette, and it satisfies consumers' tactile desires in a manner similar to that of any other cigarette. Eclipse contains materials (filters, paper, reconstituted tobacco) common to other cigarettes, and the filter and tobacco segments are produced on standard cigarette-making machines. As with all cigarettes, flavor and nicotine are derived from tobacco smoke produced by combustion, and even the number of puffs taken is similar to that for other cigarettes. Most fundamentally and dispositively, Eclipse, like all cigarettes, is lit and burned in order to derive smoking pleasure.

For all these reasons, petitioners' claim that "Eclipse bears no resemblance to a traditional tobacco product," see Petition, at 1, is simply false. Indeed, the Bureau of Alcohol, Tobacco, and Firearms ("BATF") ruled five years ago that Eclipse is a "cigarette" and subject to regulation – and taxation – as such:

ECLIPSE is a product consisting of a roll of tobacco wrapped in paper and other substances not containing tobacco. Therefore, ECLIPSE is a cigarette as within the meaning of 26 U.S.C. 5702(b) and 27 CFR 270.11. As such, ECLIPSE is taxable under 26 U.S.C. 5702.

Letter from Jerry Bowerman, Chief, Wine, Beer and Spirits Regulations Branch, BATF, to John L. Millar, Director of Taxation, R.J. Reynolds Tobacco Company (May 17, 1996) (attached as Exhibit D).⁹ Because the definition of "cigarette" in

⁹ The government of Germany also has classified HI•Q, a Reynolds product analogous to Eclipse, as a "cigarette." See Letter from Richard M. Cooper to Dockets Management Branch, Dkt. No. 94P-0456, (July 30, 1996).

26 U.S.C. § 5702(b) is identical to that in the FCLAA, 15 U.S.C. § 1332, this ruling by BATF requires the conclusion that Eclipse is within the scope of the FCLAA and therefore is within the rationale of Brown & Williamson and outside the scope of the FDCA.

In seeking a contrary determination from FDA, petitioners cite certain differences between Eclipse and other cigarettes. Petitioners claim that Eclipse “is contained in a hard casing, not wrapping paper” that remains intact after use. Petition, at 14-15, 19. Petitioners also note that Eclipse is “activated by lighting a carbon tip at the end of the casing, not by lighting and burning paper.” Id. at 14. Petitioners further observe that Eclipse “[d]oes 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.” Id.

None of the these allegations of physical differences, even if accurate,¹⁰ warrants classifying Eclipse as something other than a cigarette for purposes of the tobacco-specific legislation addressed in Brown & Williamson. During the last five decades, cigarette manufacturing has incorporated a host of new technologies – reconstituted tobaccos, filter technologies, new types of cigarette papers, expanded tobaccos, flavoring components, and others. See pp. 23-27, infra. None of these

¹⁰ See p. 16, supra (Eclipse is wrapped in conventional cigarette papers and in laminates of cigarettes papers and food-grade aluminum foil, not, as petitioners assert, in a “hard casing”).

new technologies was what "Congress had in mind when it acted in the area of traditional tobacco products." See Petition, at 15. Nonetheless, the products embodying those technologies and marketed for smoking taste and pleasure were and are – and were and are universally recognized as being – cigarettes – and the U.S. Government regulates and taxes them accordingly.

The same is true of Eclipse. As we said to the Agency in 1988 with respect to Premier, a predecessor of Eclipse:

[I]nternal parts and operation are not determinative of (i) whether or not a product is a cigarette, or (ii) whether or not its intended use is for smoking taste and pleasure or for something that would warrant classifying it as a drug or device. A Ford Escort and a Mercedes Benz 300SD are both automobiles, intended for covered, engine-propelled passenger transportation on roads, even though one has a gasoline engine and the other, a diesel engine. A Kodak and a Polaroid are both cameras, even though technologically they are very different.

Comments of R.J. Reynolds Tobacco Company, FDA Dkt. Nos. 88P-0155/CP, 88P-0155/CP0002, at 5 (Aug. 12, 1988).

Eclipse, accordingly, is subject to the same statutes as are all other cigarettes. Among other things:

- Reynolds has, since 1996, submitted to the Department of Health and Human Services information regarding Eclipse's ingredients. See 15 U.S.C. §§ 1335a, 4403; 42 U.S.C. § 290aa-2(b)(2)-(3). The Department has never rejected such submissions, as it would if Eclipse were not a cigarette.
- Advertising for Eclipse carries warnings from the Surgeon General. See 15 U.S.C. §§ 1333(c), 4402(a)-(d).

- Reynolds does not and will not advertise Eclipse on television or radio. See 15 U.S.C. §§ 1335, 4402(f).
- Advertising for Eclipse is subject to regulation by the FTC. 15 U.S.C. §§ 45, 1336.
- Eclipse is subject to the same cigarette-specific taxes as other cigarettes. See pp. 18-19, supra.

Unlike all of the other products invoked by petitioners as potentially analogous to Eclipse (cough medicines, tobacco-free cigarettes, and nicotine gums, patches, and inhalers),¹¹ Eclipse is subject to this tobacco-specific legislation because it meets the statutory definition of “cigarette” – i.e., it is a “roll of tobacco wrapped in paper or in any substance not containing tobacco.” Under the holding of Brown & Williamson, therefore, Eclipse is not subject to FDA regulation as a “drug” or “device.”

B. Eclipse Falls Within the Customary Definition of “Cigarette.”

A major thesis of the Petition is that, because Eclipse embodies technology different from that embodied in other cigarettes marketed today, it is not a simple agricultural product, and therefore is not a cigarette at all. See, e.g., Petition, at 14-15. Modern cigarettes, however, no longer consist merely of tobacco and paper. They include flavoring agents, filter components, processed tobaccos, and several types of specialty papers. For many years, manufacturers have used sophisticated technologies and additives to tobacco to create a wide array of

¹¹ See Petition, at 8 & n.10 (“Jazz” tobacco-free cigarettes), 8-9 (“GumSmoke” tobacco-flavored chewing gum), 11 (nicotine patches and inhalers), 13-14 (cough syrup), and 15 (a hypothetical nicotine gum incorporating ground tobacco).

cigarettes from which adult smokers can choose. Eclipse also incorporates sophisticated technology and additives to tobacco, but it is only one in a series of technological innovations intended to expand the variety of enjoyable cigarettes offered to adult smokers, and to reduce the yields of compounds in cigarette smoke.

1. Early Cigarettes.

Tobacco has been smoked for more than 300 years. Pipes and cigars were more popular in the early years of smoking because it was inconvenient to hand-roll cigarettes. In the late 19th century, machines were developed so that cigarettes could be rolled economically before sale. Moreover, the introduction of cigarette-making machines also enabled adult smokers for the first time to purchase cigarettes of uniform character and consistently high quality.¹²

The early cigarettes were primarily cut tobacco (much like pipe tobacco) wrapped in paper. The quality of a cigarette depended primarily on the single type of tobacco it contained – Turkish tobacco was used in premium cigarettes, and domestic “air-cured” or “flue-cured” tobacco was used in less expensive cigarettes. The first “American blend” cigarette, which combined both Turkish and domestic tobacco, was Reynolds’s Camel brand, introduced in 1913.

¹² A detailed review of the development of technologies involved in manufacturing cigarettes may be found in Tobacco: Production, Chemistry, and Technology 346-397 (D. Layten Davis & Mark T. Nielsen eds., 1999). See also, e.g., U.S. Dep’t of Health, Education, and Welfare, Smoking and Health: A Report of the Surgeon General 14:108-14 (1979) (“1979 Surgeon General’s Report”) (14-103 to 14-113) (discussing efforts in recent decades to reduce toxic agents in cigarette smoke); Colin L. Browne, The Design of Cigarettes 4-6 (3d ed. 1990) (discussing lowering of tar and nicotine yields since the 1950s); id. at 1-2 (summarizing development of cigarette filters).

Although slightly different blends and different materials were used in cigarette manufacturing and for preservation of the tobacco, cigarettes remained generally unchanged until the early 1950s. At this point in time, the U.S. market consisted of a dozen or so brands that yielded cigarette smoke with 35-40 mg. of "tar" and 2.4-3.0 mg. of nicotine (as would be measured using current FTC-prescribed scientific methods and standards).

2. Design Modifications.

Since the 1950s, manufacturers have responded to consumer demands for lower yields by pursuing three lines of research and development – (i) exploration of substitutes for tobacco; (ii) application of technology to remove or reduce individual constituents of tobacco smoke identified by public health authorities as associated with health risk, and (iii) development of new technologies to reduce yields of "tar" and nicotine.

a. Tobacco substitutes.

There has long been interest in natural tobacco substitutes. Early patents were issued for the following potential substitutes: Indian corn leaves (1855); herb buck bean (1869); eucalyptus leaves (1869); cornstalk piths (1870); spikenard (1878); lettuce, potato, corn, peanut, and spinach leaves (1951); bagasse (1957); papaya leaves (1960); corn silk and alfalfa (1960); sagebrush (1962); and grated or ground corncobs (1963). Of these, only vegetable-leaf cigarettes (e.g., lettuce-leaf cigarettes) were ever commercially marketed in the United States. They failed commercially, however.

Undaunted by these early failures, between 1966 and 1975 researchers around the world sought to develop either a natural tobacco substitute or synthetic substitutes that would be used either alone or in a blend with tobacco. Many patents were issued for tobacco substitutes during that period. They involved such varied substances as woodpulp, cellulose, carbon or graphite fibers, beet pulp, polysaccharides, alkylvalerolactones, "nonwoody" plants, and ammonium phosphate.

Tobacco substitutes failed worldwide, even after they were blended with tobacco. The low "tar" and nicotine products developed through other technological advances in cigarette design were simply accepted by consumers as superior products.

b. Removal of individual constituents.

During the 1950s and 1960s, cigarette manufacturers explored various methods to reduce individual constituents in cigarette smoke, e.g. using additives in the cigarette paper or the tobacco, using expanded tobaccos, selecting tobacco blends, and adding different types of filters or other filtration mechanisms to the cigarette. The early filters or "plugs" varied, but the basic technology involved a porous material wrapped in a paper "plug-wrap" and affixed to the end of the cigarette's tobacco column by an adhesive. By varying the composition and density of the "plug" or filter, designers varied the volume and composition of the mainstream smoke.

The most notable development resulting from those efforts was the attached filter. Today, however, it is the general reduction of the overall delivery of

many smoke constituents, not their filtration of individual constituents, that is the reason for using filters.

c. Reductions in "tar" and nicotine.

The introduction of filters and other efforts to remove individual constituents brought about a dramatic decline in the amount of "tar" and nicotine yielded by cigarettes. Design changes such as the development of more porous cigarette paper, improved filtration, air dilution, the use of expanded (or "puffed") tobacco, and reconstituted tobacco sheets made these reductions possible.¹³

Cigarette designers were so successful in their efforts to respond to the demand for these reductions that today there are commercially available cigarettes that yield "tar" and nicotine at levels so low they cannot be measured reliably by the FTC's standard procedure.¹⁴ In 1979, the Surgeon General listed more than 25 different design techniques that reduce yields of "tar" and nicotine.¹⁵

¹³ Filtration and the discovery of reconstituted tobacco were two major breakthroughs. Filtration alone reduced "tar" yield by as much as fifty percent in some commercial brands. See Mitchell & Gieske, Mechanical Filtration: Review of Filtration Mechanisms Pertinent to Cigarette Smoke, in Toward a Less Harmful Cigarette, National Cancer Institute Monograph 130-31 (1968).

¹⁴ See, e.g., Federal Trade Commission Report, "Tar", Nicotine and Carbon Monoxide of the Smoke of 207 Varieties of Domestic Cigarettes 2-3 (Jan. 1985).

¹⁵ See 1979 Surgeon General's Report 14:108-14 (1979) (identifying techniques involving, inter alia, the genetics and breeding of tobacco plants, planting density, fertilization, applying agricultural chemicals, topping the tobacco plant at different stages, altering the type of tobacco, selecting tobacco with specific constituents, leaf curing, grading, fermentation, solvent extraction, freeze-drying, additives, blending, changing the amount of tobacco and/or tobacco stems, utilizing varying amounts of reconstituted tobacco, varying the tobacco cut, using porous cigarette paper, perforating the cigarette paper,

After 1965, the principal design breakthroughs were expanded tobacco and air dilution through perforation of cigarette filters. Expanded tobacco resulted from the search for ways to reduce the volume of tobacco in each cigarette in order to reduce "tar" and nicotine yields. The tobacco is "puffed" or expanded by impregnating it with a liquid expansion agent and then exposing it to hot air so that its volume expands. As a result, each cigarette can be filled with less weight of tobacco, and the yields of "tar" and nicotine are reduced. Reynolds developed expanded tobacco in 1968, and was the first to introduce it commercially shortly thereafter. By 1981, the tobacco content by weight of the average cigarette had declined by 23.8% through the use of expanded tobacco,¹⁶ and, in some ultra low-"tar" brands, expanded tobacco was used to a much greater extent to reduce the weight even more dramatically. Thus, as part of the design strategy to achieve lower yields of "tar," nicotine, and other smoke constituents, the amount of tobacco in cigarettes has been reduced.

In the late 1960s, scientists discovered that perforating the cigarette filter allows air to mix with the mainstream smoke, thereby diluting the smoke and reducing the total "tar," nicotine, and carbon monoxide inhaled. Perforated filters

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smoke filtration, and perforating the filter tips). Many of these processes are used by virtually all cigarette manufacturers today.

¹⁶ U.S. Dep't of Health and Human Services, The Health Consequences of Smoking: The Changing Cigarette, a Report of the Surgeon General 209-10 (1981).

were first sold commercially in about 1972. By 1981, approximately 50% of all cigarette brands sold had perforated filters.¹⁷

3. Eclipse.

When the first filter was introduced in the 1950s, someone might have argued that a roll of tobacco with an attached filter was not a “cigarette” because no cigarette with a filter had ever existed before, because the filter was not, itself, subject to combustion, and because filter cigarettes (unlike more “traditional” cigarettes) did not burn down completely when smoked. Similar arguments might have greeted the first use of expanded tobacco, reconstituted tobacco sheets, perforated filters, humectants, preservatives, cigarettes containing burn additives, or flavorings. All such arguments would have been wrong: today, the cigarettes on the market differ widely in their embodied technologies – from unfiltered to those with highly sophisticated filtration and air dilution systems; yet, we regard all cigarettes – those that incorporate these various technologies and those that do not – as cigarettes, without qualification. The same is true of Eclipse.¹⁸

Thus, although Eclipse primarily heats, rather than burns, tobacco, see Petition, at 3, 14-15, it continues the strategies that have shaped the evolution of cigarette technology since the 1950s. As with expanded tobacco technology, Eclipse seeks to achieve acceptable tobacco smoking taste, aroma, and pleasure

¹⁷ Id. at 97.

¹⁸ The same is true, of course, of foods: most are no longer the same as what “mother used to make.” See, e.g., Richard A. Merrill & Earl M. Collier, “Like Mother Used To Make”: An Analysis of FDA Food Standards, 74 Colum. L. Rev. 561 (1974).

while reducing the amount of tobacco burned. As with other modern cigarettes that use air dilution or filter perforation technologies, Eclipse alters the composition of inhaled smoke by modifying the mechanisms by which tobacco smoke is produced (by primarily heating, rather than burning, the tobacco).

In other cigarettes, nicotine and other flavoring and aromatic constituents are released from tobacco into smoke; in Eclipse, nicotine and other flavoring and aromatic constituents are released from tobacco into smoke. In other cigarettes the release results from the burning (primarily) and heating of tobacco; in Eclipse the release results from the heating (primarily) and burning of tobacco. For purposes of FDA jurisdiction, the difference is utterly immaterial.

In sum, Eclipse is a roll of tobacco wrapped in paper; it is lit at one end, and at the other end the smoker draws smoke through a hollow cellulose acetate filter. Some of the tobacco in Eclipse does burn, as does tobacco in other cigarettes. More importantly, the intended use and function of Eclipse are the same as those of any other cigarette: to provide smoking taste and pleasure to adult smokers. Like many other modern cigarettes, Eclipse also seeks to reduce yields of “tar,” nicotine, and other smoke constituents. Eclipse thus is not merely like a cigarette; it is a cigarette for all purposes relevant to FDA jurisdiction.¹⁹

¹⁹ Eclipse also satisfies FDA’s definition of “cigarette” in its former tobacco regulations. See 21 C.F.R. § 897.3(a) (1998). It is a “product which contains nicotine, is intended to be burned under ordinary conditions of use, and consists of . . . [a] roll of tobacco wrapped in paper or in any substance not containing tobacco . . .” *Id.* That Eclipse contains ingredients in addition to tobacco and paper does not prevent it from satisfying this definition just as

IV. CLAIMS REGARDING THE ADVERTISING OF A TOBACCO PRODUCT ARE APPROPRIATELY ADDRESSED BY THE FEDERAL TRADE COMMISSION, NOT BY FDA.

Petitioners urge the FDA to review the promotional materials for Eclipse on the ground that “there is no evidence before FDA to demonstrate that Eclipse is a safe product” and that “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.” Petition, at 21. They concluded that “for FDA to decline to regulate Eclipse would be to create an 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.” *Id.* at 21-22.

The “immense regulatory void” identified by petitioners is a fiction. The federal government clearly has a key role in preventing misleading advertising and consumer confusion in connection with the advertising of over-the-counter products. Generally, however, the appropriate agency for such oversight is the Federal Trade Commission, not the FDA. The FTC has authority over advertising claims for tobacco products sold over the counter, 15 U.S.C. §§ 45, 1336; FDA does not. The FTC also polices the market vigorously, and it clearly has the institutional expertise and resources to review the merits of scientific claims regarding Eclipse and similar products. Indeed, many of the same petitioners that filed the instant

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the fact that other cigarettes contain additional ingredients does not prevent them from satisfying it.

Petition have made the same product (Eclipse) and promotional claims (by Reynolds) the subject of petitions to the FTC. The “government scrutiny” urged by petitioners, see Petition, at 21, falls appropriately within the jurisdiction of the FTC, not FDA.

V. EXERCISING JURISDICTION WOULD DETER THE DEVELOPMENT AND MARKETING OF OTHER REDUCED-RISK PRODUCTS.

Not only would the exercise of jurisdiction by FDA be unwarranted by the facts and contrary to law, it also would be bad policy. Were the FDA to classify Eclipse as a drug or device, it would have the perverse effect of precluding manufacturers of tobacco products from developing, marketing, and informing adult smokers about reduced-risk cigarettes.²⁰ Because such products inherently possess some degree of risk and are not intended to be effective for any therapeutic use, Eclipse and similar reduced-risk cigarettes never could be shown to be “safe” and “effective,” FDCA §§ 505(d)(1), (2), (4) & (5), 515(d)(2)(A)-(B), 21 U.S.C. §§ 355(d)(1), (2), (4) & (5), 360e(d)(2)(A)-(B), or otherwise meet the standards of the FDCA for approval of drugs and devices.²¹ Exercising jurisdiction in this case thus would lead

²⁰ This would not be the only perverse result of accepting petitioners’ arguments, which apparently would broaden FDA’s jurisdiction to encompass all products that “affect the structure or . . . function of the body of man” and are marketed as posing lower risks than do other products made available by competitors. See Petition, at 18-19. Thus, petitioners offer no principled rationale as to why, under their view, FDA’s jurisdiction would not grow to encompass other reduced-risk but non-therapeutic products such as reduced-risk guns, toys, exercise equipment, or even roller coasters. The ensuing regulatory bottleneck clearly would, among other things, inhibit the development of such reduced-risk products and thereby work contrary to the public interest.

²¹ Were FDA to assert jurisdiction over Eclipse and similar reduced-risk tobacco products, the Agency would be compelled to deem such products unapproved

the Agency to preclude those who continue to smoke from being able to choose the very products that pose the least risk.

In sum, FDA does not have jurisdiction over Eclipse.

Conclusion

For the foregoing reasons, the Petition should be denied.

Respectfully submitted,



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Dated: April 9, 2002

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new drugs under FDCA §§ 301(d), 505, 21 U.S.C. §§ 331(d), 355, or devices under FDCA §§ 501(f), 515, 21 U.S.C. §§ 351(f), 360e. FDA also would be required to deem such products to be misbranded and therefore unlawful pursuant to 21 U.S.C. § 352(j) (deeming a drug or device misbranded if “it is dangerous to health when used in the . . . manner . . . suggested in the labeling thereof”), § 352(f)(1) (requiring adequate directions for safe use), and § 352(f)(2) (requiring “adequate warnings against use . . . by children”). Upon a finding of a reasonable probability that such a product “would cause serious, adverse health consequences or death,” FDA also would be compelled to issue a cease-distribution order pursuant to 21 U.S.C. § 360h(e)(1). Part of the basis for the decision in Brown & Williamson is that the FDCA cannot accommodate the ongoing marketing of tobacco products, which do not have therapeutic benefits that outweigh their risks, however reduced. See Brown & Williamson, 529 U.S. at 142.