

IN THE FOOD AND DRUG ADMINISTRATION

)
Petition for Regulation of)
Vector’s “OMNI” Cigarettes)
And Star Scientific’s and)
Brown & Williamson’s “Advance”)
Cigarettes)
)

Docket No. _____

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 Association 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

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, Eclipse, 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. In the case of Advance and OMNI, which are the subjects of this petition, the manufacturers have made explicit health claims about these products, but are marketing the products without first submitting them or the claims made about them to FDA for approval or without going through any government review. As we demonstrate in this petition, OMNI and Advance are 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 OMNI and Advance until the manufacturers have complied with the law.

OMNI and Advance

OMNI and Advance are two so-called “reduced risk cigarettes” that have recently become available in the stores in the United States. Vector Group, Ltd. (“Vector”) has recently begun selling OMNI in retail stores across the United States. At the same time, Brown and Williamson Tobacco Corporation (“Brown & Williamson”) has recently begun test-marketing Advance, which it jointly developed with Star Scientific, Inc. (“Star”). Both Vector, on behalf of OMNI, and Star and Brown & Williamson, on behalf of Advance, have claimed that their products are less dangerous than traditional cigarettes, and provide smokers with a safer, better alternative to those cigarettes.¹

A. Action Requested

Petitioners request FDA to require premarket approval of OMNI and Advance under the FDCA. Specifically, this petition requests that the FDA classify, and therefore regulate, OMNI and Advance as “drugs” within the meaning of that statute.

¹ Star and Brown & Williamson developed Advance using Star’s “StarCured” tobacco and Brown & Williamson technologies for scientific testing and test marketing. Under an agreement between the two companies, Star conducted the initial test marketing of Advance and Brown & Williamson took over marketing of Advance as of November 2001. *See* Securities and Exchange Commission Form 8-K, filed by Star Scientific at § 2.01 (April 25, 2001) (Attachment A), available at http://eol.finsys.com/edgar_cov_html/2001/05/17/0000931763-01-500694.html; Press Release, Star Scientific, Inc., “Star Scientific, Inc. Issues Statement on Brown & Williamson’s Test Market Launch of Advance Low-TSNA Cigarette Using StarCured Tobacco, Confirms Imminent Test Market of Ariva”, (November 6, 2001) (hereinafter “Star November 6, 2001 Press Release”) (Attachment B). available at http://www.starscientific.com/frame_pages/release_frame.htm

B. Statement of Grounds

The health claims made by Vector and Star/Brown & Williamson with respect to OMNI and Advance, respectively, and the companies' use of these claims in marketing their products bring OMNI and Advance within the FFDCA's definition of a drug, and subject these products to regulation by the FDA. The Agency has traditionally and consistently determined that products, including tobacco products, that are advertised as therapeutically beneficial or whose claims can reasonably be interpreted by consumers to be claims of therapeutic benefit are subject to the jurisdiction of FDA and must receive rigorous, independent scrutiny by the FDA in order to determine whether the representations of beneficial effect have an adequate scientific basis. Vector has made such health claims with respect to OMNI and Star/Brown & Williamson have made such claims with respect to Advance. These claims have not been subjected to rigorous scientific scrutiny, nor have they been verified or assessed or submitted for approval by the FDA. It is the obligation of the FDA to ensure that Vector's and Star's/Brown & Williamson's claims, like the claims of any manufacturer purporting to sell a therapeutically beneficial product, are held to the same scientific standards and the same level of Agency review as any other product for which health claims are made.

1. Background on OMNI

OMNI has just been made available in retail stores across the United States. OMNI smokes, burns, and tastes like a conventional cigarette, but there is nothing conventional about the claims Vector is making about this product. Vector's claims for OMNI are bold and are clearly intended to communicate a health message – *i.e.*, that OMNI is safer than and therefore a

“better alternative” to traditional cigarettes.² The title of one OMNI ad is “**The First Reduced Carcinogen Cigarette**”. Attachment C. Other ads feature the statement, “**Introducing the first premier cigarette created to significantly reduce carcinogenic PAHs, nitrosamines and Catechols, which are the major causes of lung cancer in smokers**”. Attachment D. The text of an Open Letter ad placed in numerous newspapers elaborates:

However, the medical community has identified specific carcinogens that are a major cause of lung cancer in smokers. In a groundbreaking move, we have greatly reduced many of these.

Let me be perfectly clear – there is no such thing as a safe cigarette and we do not encourage anyone to smoke. But, we strongly believe that if you do smoke, OMNI is the best alternative.

While OMNI has not yet been proven to reduce health risks, the significant reduction of carcinogen levels is in our opinion a major step in the right direction.

Attachment C. Along with another of its new products, “OMNI Free” cigarettes³, OMNI is the subject of a \$100 million advertising campaign in which Vector promotes its “less hazardous” smoking products.⁴

² See “Vector Tobacco’s New Reduced Carcinogen Cigarette Scores High In Taste Tests Against Leading Premium Brand,” *Business Wire*, September 28, 2001 (quoting Vector Chairman Bennett LeBow) (“While there is no such thing as a safe cigarette, we believe that a premium taste, reduced carcinogen cigarette such as Omni provides smokers with a better alternative.”)

³ Like OMNIs, OMNI Free cigarettes are claimed to have fewer cancer-causing agents than traditional cigarettes. OMNI Free cigarettes are also purported to be nicotine-free, and therefore non-addictive. See “Genetically Modified Tobacco Plants Yield Nicotine-Free Cigarettes,” *Environmental News Network*, July 30, 2001. Vector has indicated that it plans to make OMNI-Frees available in stores in early 2002. Vector has also stated that it intends to seek FDA approval to market OMNI Free as a smoking-cessation device. *Id.*; Andrea Knox, “A Swirl of Debate Over New Cigarette,” *Philadelphia Inquirer*, April 15, 2001 (noting that Vector “will seek approval from [FDA] to market Omni Free for use as a stop-smoking aid”). In light of Vector’s apparent concession that FDA regulation of Omni Free is appropriate, this Petition addresses only the need for FDA regulation of OMNI, not OMNI Free.

⁴ See Brian Louis, “Vector Plans to Roll out OMNI in Second Half of October,” *Winston Salem Journal*, October 6, 2001.

Vector claims to have achieved this result through “a proprietary process in which regular tobacco is treated with a complex catalytic system, thereby significantly reducing the carcinogenic levels.”⁵ According to Vector, its new technology “will eliminate one of the most serious cancer causing agents from tobacco smoke.”⁶ Vector’s health claims for OMNI are, of course, central to the company’s multimillion dollar advertising campaign for its product, the tag line of which is “Reduced Carcinogens. Premium Taste.”⁷ In pointing out the health-related virtues of OMNI, Vector Chairman Bennett LeBow has indicated, the company “is going to quote the public-health people and the results of our tests . . . and just let people draw their own conclusions.”⁸

2. Background on Advance

Brown & Williamson recently announced it is test marketing “Advance Lights,” which it claims “combines two important new technologies” to “reduce the levels of many toxins.”⁹

⁵ *Id.*

⁶ “Vector Plans Reduced Risk Cigarettes,” *New York Times-AP*, February 14, 2001 (quoting Vector Spokesperson Brandy Bergman). *See also* “Company Says New Cigarette Safer,” *Washington Post-AP*, October 7, 2001 (“While there is no such thing as a safe cigarette, we believe we’ve eliminated what the health community considers to be the most serious cancer causing agents . . .”)(quoting Bennett LeBow, Vector Chairman).

⁷ Attachments C & D. *See also* “As Bennett LeBow’s Reduced Carcinogen Cigarette Hits Stores, He Does a Slow Burn Over His Competitors,” *Broward Daily Business Review*, October 19, 2001.

⁸ “Vector Vows to Beat Competitors in Race to Produce ‘Safer’ Cigarette,” *Wall Street Journal*, February 13, 2001 (hereinafter *Wall Street Journal*) (quoting Bennett LeBow, Vector Chairman).

⁹ Press Release, Brown & Williamson Tobacco Co., “Brown & Williamson Tobacco Tests New Advance Lights Cigarette: New Technologies Reduce the Levels of Many Toxins While Delivering Smooth Taste”, *available at* http://www.brownandwilliamson.com/index_sub2.cfm?Page=/NR/Index.cfm (November 5, 2001) (Attachment E) (hereinafter “Brown & Williamson Tests Advance”).

The two technologies are “a special three-part Trionic filter”¹⁰ and a tobacco cured using a special method, patented by Star Scientific, Inc. (“Star”). Star claims its new method “consistently produces flue-cured tobacco with the lowest levels of tobacco specific nitrosamines (‘TSNAs’) in the world.”¹¹ Brown & Williamson and Star jointly developed Advance, and Star conducted the initial test marketing. Both companies have made statements to the public regarding Advance.

Both companies have contended they are not marketing Advance as a less dangerous cigarette, but their public pronouncements suggest otherwise. Brown & Williamson’s advertising slogan is “Advance: All of the taste . . . Less of the toxins.”¹² As was the case when Star marketed the product, packages of Advance will come with a pamphlet (“onsert”) that “shows how much the major toxins contained in cigarette smoke are reduced compared to leading Lights brands.”¹³ Both companies note that the improvements they tout in Advance do not mean it is a safe cigarette. But the disclaimer is undermined by both companies’ consistent linkage of the filtering and curing technologies used in Advance with reduced risks for smokers, and by their repeated suggestions they have produced a less toxic cigarette. In the minds of consumers, the disclaimer will not prevent the product as being perceived as less of a health risk.

For example, Star’s public statements are laden with references to the less toxic – *i.e.*, safer – nature of Advance as compared to traditional cigarettes. *See, e.g.*, Press Release, Star

¹⁰ *Id.*

¹¹ *See* “Star November 6 Press Release”, *supra* n.1

¹² Advance Onsert (a brochure attached to the packaging), *available at* <http://www.brownandwilliamson.com/apps/pdf/advanceonserts.pdf> (last visited November 7, 2001) (Attachment F).

¹³ “Brown & Williamson Tests Advance”, *supra*, n.9. *See also Id.*

Scientific, Inc., “Star Scientific and B&W Enter Into Contracts for Purchases of StarCured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products” (April 27, 2001) (“[Star] believes Advance is the first premium, conventional cigarette that delivers substantially less cancer-causing toxins . . . than the two leading light cigarette brands”) (Attachment G); Press Release, Star Scientific, Inc., “Star Scientific, Inc., Begins a 2-State Test Market of the First and Original Premium Conventional Cigarette Brand – Advance – Manufactured to Deliver Less Carcinogenic Toxins” (October 2, 2000) (touting Advance as “the first and original premium cigarette to be manufactured so that the cigarette delivers less cancer causing toxins . . .”) (Attachment H); *id.* (“Star believes it has now developed a technology . . . that significantly reduces the delivery of some of the known cancer causing toxins”); “New Standards for the Labeling and Marketing of Tobacco Products: Background Statement by Star Scientific, Inc., Concerning the Initial Test Marketing of Advance” (“Star Background Statement”) (touting Advance as “the first conventionally-manufactured cigarette that delivers significantly less tobacco specific nitrosamines”) (Attachment I); Statements of Star Chairman Paul Perito in Adrian Zawata, “Low-nitrosamine cigarettes go on sale,” *Tobacco Reporter*, October 3, 2000 (“[Star] ha[s] an obligation to make Advance available to adult tobacco consumers along with information about the comparable toxic effects of smoke . . . Star hopes that the start of its limited test market of Advance will serve as an incentive to the traditional tobacco industry to consider producing and appropriately labeling less-toxic cigarette products in a similar fashion.”)

Similarly, Brown & Williamson’s “onserts” claim a patented tobacco curing process that “significantly inhibits the formation of [TSNAs], a group of toxins in tobacco and tobacco smoke.” And about the “Trionic filter,” Brown & Williamson says:

The Trionic filter was developed to decrease the levels of many of the principal toxins found in cigarette smoke. This was accomplished by first studying the various constituents that make up cigarette smoke and then engineering a filter that reduces many of these components . . . The result . . . is a significant reduction in many of the toxins in cigarette smoke.¹⁴

3. OMNI and Advance are “drugs” for purposes of 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, Vector and Star/Brown & Williamson have expressly represented in their promotional materials and public statements that their products can mitigate or prevent diseases normally associated with smoking. For this reason, OMNI and Advance both meet the FFDCA’s definition of a “drug,” and are subject to FDA regulation.¹⁵

FDA’s longstanding practice has been to treat as drugs products that claim, and are intended, to confer health benefits on consumers. Both OMNI and Advance have been promoted and marketed with statements that users of these products may be less likely than conventional cigarette smokers to develop cancer or other diseases.¹⁶

¹⁴ “Advance Lights Media Press Kit: Trionic Filter,” *available at* <http://www.brownandwilliamson.com/NR/Index.cfm?ID=280&Sect=3> (last visited November 7, 2001) (Attachment J).

¹⁵ Brown & Williamsons’s materials are the most vague, more commonly using the term “toxins” rather than “carcinogens” to describe TSNAs. They still make the connection, however, noting that some TSNAs “are categorized as carcinogens by the International Agency for Research on Cancer.” “Brown & Williamson Tests Advance”, *supra* n. 9. The message to consumers is the same: the product contains fewer substances harmful to the body. That they are less specific about the disease is not meaningful in an environment where it is well known that smoking causes cancer. They could also be read as more expansive claims, attempting to encompass more diseases that are associated with smoking.

¹⁶ 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

That OMNI and Advance are tobacco products makes no difference. While the United States Supreme Court in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), held that FDA does not have jurisdiction to regulate traditional tobacco products, the Court’s holding was limited to such 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).¹⁷

Indeed, FDA has regularly claimed jurisdiction over tobacco products that, like OMNI and Advance, were claimed as safer, healthier alternatives to traditional 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, like OMNI and Advance, as “a smoke that is actually better for your health than any other cigarette.” See advertisement for Fairfax cigarettes (Attachment K). Some of the claims for Fairfax were similar to the claims for OMNI and Advance – 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

advertising or other promotional materials. *E.g.*, *Action on Smoking & Health v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980).

¹⁷ The Court in *Brown & Williamson* 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. Thus, FDA retains authority to regulate tobacco products – even cigarettes and smokeless tobacco products – when these products bear health claims.

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. thermocouple. The findings showed that 91 per cent of those tested disclosed no clinical evidence of any constriction.

Attachment K. FDA's position regarding tobacco products bearing health claims was reasserted both in 1972 and 1988, when the FDA Commissioner testified before Congress that cigarettes claiming beneficial physical effects were to be treated as drugs under the FDCA.¹⁸

More recently, in 1992, the FDA addressed "Jazz" cigarettes, which were marketed as a nicotine-free "safe cigarette."¹⁹ 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."²⁰ 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 FDCA, requiring approval of a New Drug Application.²¹

¹⁸ 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).

¹⁹ Letter from Richard J. Chastonay, Director, Division of Drug Labeling Compliance, FDA, to Alan V. Phan, Harcourt Export Co. (September 30, 1992) (Attachment L).

²⁰ Advertisement for Jazz Cigarettes (Attachment M); *see also Id.*

²¹ Letter from Chastonay to Phan, *supra* n.19, at 2.

Finally, in 1997, FDA addressed another Star product called “GumSmoke,” a tobacco-flavored chewing gum. Among the claims made for GumSmoke by Star was that the product would contain specially processed tobacco that, like the tobacco used in OMNI, was “TSNA-free.”²² FDA objected, 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.”²³ 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.”²⁴

There can be no dispute that Vector and Star/Brown & Williamson, like the manufacturers of Fairfax Cigarettes, Jazz Cigarettes, and Gumsmoke, are claiming that their products are “safer substitute[s] for smoking conventional cigarettes.” Thus, like those products, OMNI and Advance are expressly intended “for use in the mitigation . . . or prevention” of diseases associated with smoking. 21 U.S.C. § 321(g). Both products fall within the FFDCA’s definition of “drug,” and are subject to regulation by the Agency.

Vector and Star/Brown & Williamson have taken the position that simply because the companies have made factual statements about the reduced carcinogen levels in their product

²² 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 N).

²³ *Id.*

²⁴ *Id.*

does not mean that they are making health claims with respect to those products.²⁵ FDA rejected this very argument in the context of GumSmoke. The manufacturer of GumSmoke simply noted that the product was TSNA-free – a factual claim like Vector’s claims that OMNI contains reduced carcinogens, and like Star’s/Brown & Williamson’s similar claim for Advance. FDA determined that such factual claims could create the perception that the product was a safer alternative to conventional tobacco, and therefore amounted to health claims that brought GumSmoke within the Agency’s jurisdiction. This case is no different: Vector and Star/Brown & Williamson have made factual statements regarding the reduced toxin and carcinogen levels delivered by their products that would lead the consumer to believe that those products are safer than traditional cigarettes.

Vector and Star/Brown & Williamson have also taken the position that because they are not asserting that OMNI or Advance confer affirmative health benefits on users, but merely that they “may present smokers with less risk compared to” traditional cigarettes, they are not making any health claims regarding their products. Put simply, these companies are claiming that there is a difference between “reduced-risk” claims of the kind they are making with respect to OMNI/Advance, and health claims over which FDA may exercise jurisdiction. The FDA has rejected this argument, and should do so again.²⁶

²⁵ See, e.g., Transcript of Vector Group, Ltd. Second Quarter Conference Call, August 15, 2001, at 18-19 (Attachment O) (noting that a claim of less carcinogens is simply measurement data, and not claims regarding the health-related attributes of the product).

²⁶ Vector and Star/Brown & Williamson repeat the mantra that “there is no such thing as a safe cigarette.” E.g., *Wall Street Journal*, *supra* n.8 (quoting Bennett LeBow, Vector Chairman); “Tobacco Company Tests a Less-Toxic Cigarette,” *New York Times-AP*, October 3, 2000 (noting that packets of Advance come with a warning stating that “there is NO such thing as a safe cigarette”); Advance Onsert, *supra* n. 12.

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. Many, if not most, smokers are addicted to nicotine, and these smokers are clearly the target audience for OMNI and Advance. Reduced-risk products like these 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 traditional tobacco products like cigarettes 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 OMNI and Advance as drugs is therefore an entirely permissible construction of the FFDCA.

Second, as a matter of agency practice, the distinction the companies attempt to draw has already been rejected by the FDA, which, as discussed above, has seen fit to regulate tobacco-related products on the grounds that those products were claimed to be safer than conventional cigarettes.

Third, the distinction between affirmative health claims and reduced risk claims makes no sense as a matter of policy. Consumers are as likely to be misled by claims of relative safety as they are by affirmative health claims. 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. Neither Star/Brown & Williamson nor Vector can dispute that their claims regarding their products are designed to convince consumers of the health benefits of using that product, or that these claims are designed to induce consumers to buy the product.²⁷ FDA can, and should, regulate Omni and Advance on the basis of these claims.

4. FDA’s assertion of jurisdiction over OMNI, Advance and other substitutes for traditional tobacco products is necessary to assure the safety of new products that are being marketed as improvements over traditional tobacco products

At the present time, there is no evidence before FDA to demonstrate that OMNI or Advance are safe products. There are dozens of known carcinogens in cigarette smoke. Notwithstanding Vector’s and Star’s/Brown & Williamson’s claims that they have reduced the most prominent of these agents in OMNI and Advance, respectively, there is no evidence to show whether reducing these particular carcinogens alone would make cigarettes less harmful or if so, whether the reduction would be significant or apply to a significant number of users.²⁸ Moreover, neither OMNI nor Advance will diminish the risk to smokers of heart disease,

²⁷ As one tobacco industry analyst has pointed out, “If you’re a smoker and you have a choice between two cigarettes, and one has high levels of carcinogens and one doesn’t, and the one with fewer carcinogens tastes the same, I would think you would gravitate toward the healthier, safer cigarette.” Joel Luton, APS Financial Corp., quoted in Anne Fawcett, “Liggett Group to Produce ‘Safer’ Cigarettes in Durham, N.C.,” *Durham Herald-Sun*, September 4, 2001. Vector itself has stated the point more bluntly: “We are not making a ‘safe’ cigarette . . . But we want to help the people who are addicted. And, quite frankly, hopefully, we’ll make a lot of money along the way.” *Wall Street Journal*, *supra* n.8 (quoting Bennett LeBow, Vector Chairman).

²⁸ “Tobacco Company Tests a Less-Toxic Cigarette,” *New York Times-AP*, October 3, 2000 (quoting Donald Shopland of the National Cancer Institute). Indeed, both Vector and Star/Brown & Williamson have conceded that their products will still contain cancer-causing chemicals. See, e.g., “New Cigarette Claimed to be Less Dangerous,” *Associated Press*, October 8, 2001 (noting concessions by Vector); Adrian Zawata, “Low-nitrosamine cigarettes go on sale,” *Tobacco Reporter*, October 3, 2000 (noting Star’s concession that there is not enough evidence to show that the Company’s methods will actually lower health risks).

emphysema, or other illnesses associated with smoking. Finally, to the extent that smokers are convinced by Vector's and Star's/Brown & Williamson's health claims, they might end up continuing to smoke or smoking *more* than they would if they were smoking traditional cigarettes, and negating any benefits from use of the "reduced-risk" products.

It is clear that any suggestions as to the benefits or risks of OMNI or Advance furnish an insufficient basis for evaluating the safety of this product. *These products must be subjected to Agency scrutiny before any conclusions are drawn as to the products' safety.*

Vector and Star/Brown & Williamson are not alone in developing allegedly reduced-risk cigarettes that are, in fact, of uncertain safety. Philip Morris and other major tobacco companies are also developing cigarettes that purportedly contain reduced amounts of cancer-causing agents. Many of these products are being, or are expected to be, marketed as safer than conventional tobacco products. The development of these nontraditional tobacco and nicotine products make it essential that FDA promptly define and articulate a consistent and scientifically rigorous approach to regulating such alleged "reduced-risk" products.

C. Conclusion

For the foregoing reasons, FDA should classify OMNI and Advance as "new drugs" which cannot be marketed absent FDA approval, and the Agency should therefore invite their manufacturers to submit "new drug" applications for their respective 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 environmental impact statement. In any event, the action requested in this petition will not have any significant effect on the quality of the human environment.

In accordance with the requirements of 21 C.F.R. § 25.15, we assert we are not aware of any extraordinary circumstances.

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
202-296-5469

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 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.

Dated: December 18, 2001