

**BEFORE THE UNITED STATES FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ROCKVILLE, MARYLAND**

**Petitions for Regulation of Vector's "OMNI"
Cigarettes and Star Scientific's and Brown &
Williamson's "Advance" Cigarettes**

Docket Nos. 01P-0571, 02P-0206

**COMMENTS OF BROWN & WILLIAMSON TOBACCO CORPORATION ON THE
PETITIONS FOR REGULATION OF BROWN & WILLIAMSON "ADVANCE"
CIGARETTES SUBMITTED BY NAT'L CENTER FOR TOBACCO-FREE KIDS, *et al.*,
AND THE SOCIETY FOR RESEARCH ON NICOTINE AND TOBACCO**

Pursuant to 21 C.F.R. § 10.30(d), Brown & Williamson Tobacco Corporation ("Brown & Williamson") submits the following comments on the Citizen Petitions filed by the National Center for Tobacco-Free Kids, *et al.*, ("NCTFK") dated December 18, 2001 (Docket No. 01P-0571) and by the Society for Research on Nicotine and Tobacco ("SRNT") dated April 23, 2002 (Docket No. 02-0206). For the reasons stated below, the Petitions should be denied.

I. NATURE OF THE PETITIONS

Each of the Petitions invites the U.S. Food and Drug Administration to regulate Brown & Williamson Advance cigarettes (as well as the product of another tobacco company) as a "drug" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.* (2000). Ignoring the United States Supreme Court's clear determination that FDA has no authority over cigarettes or other tobacco products, Petitioners allege that express or implied "health" claims

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purportedly made for Advance render the product a “drug” subject to FDA preapproval requirements.

II. BROWN & WILLIAMSON’S ADVANCE® LIGHTS CIGARETTES

Brown & Williamson now is test marketing Advance Lights cigarettes in the metropolitan area of Indianapolis, Indiana.¹ This test market began in November 2001.² Brown & Williamson does not now market Advance Lights cigarettes anywhere else.

Advance cigarettes are regulated by the U.S. Bureau of Alcohol, Tobacco and Firearms as Class A Cigarettes, and each box is labeled with that regulatory classification.³ Each box also bears a “Surgeon General’s Warning,” as required by the Federal Cigarette Labeling and Advertising Act and the Federal Trade Commission’s (“FTC”) implementing regulations.⁴ The advertising for the product, including any claims made, is regulated by the Federal Trade Commission and also contains statements in compliance with FTC requirements.⁵

A. Advance Cigarettes Product Positioning

Each Advance cigarettes package bears a pamphlet inserted between the box outer surface and its clear plastic wrapping. This information vehicle has been named a package

¹ Brown & Williamson Tobacco Corporation, based in Louisville, Ky., is the nation’s third largest manufacturer and marketer of cigarettes. In addition to Advance Lights, the company’s other cigarette brands include Kool, Filtered Pall Mall, Misty, Capri, Viceroy and GPC. Brown & Williamson does not manufacture or market any medicines or other products that are offered for therapeutic purposes. No product now manufactured or marketed by Brown & Williamson is regulated by the U.S. Food and Drug Administration.

² Two brand styles are offered: Advance Lights Kings Box and Advance Lights 100s Box.

³ Copies of the graphics currently used on the test-marketed boxes of the two Advance cigarettes brand styles appear in Exhibit 1 to this response. The side of each box says, “20 Class A Cigarettes,” in compliance with the applicable BATF regulations.

⁴ The warning in the Exhibit states, “Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.” The statute and FTC regulations require that this and other statutory warnings be rotated on cigarette packages and advertisements in accordance with a specified schedule and be presented in accordance with specified type size and style rules.

⁵ Copies of the advertising are attached in Exhibit 2. Each advertisement carries the Surgeon General’s Warning and the statement of the levels of “tar” and nicotine required by the FTC.

“onsert,” because it is placed on (rather than in) the package.⁶ Each onsert is folded so that a potential purchaser can see the following:⁷

Brown & Williamson Tobacco
is providing this information so
adults consumers have a basis
for making informed choices.

**There is no such thing
as a safe cigarette.**

ADVANCE[®]
All of the taste. . .
Less of the toxins.[™]
Reduced levels of toxins compared
to the leading lights brand styles.

There is not enough medical
information to know if Advance with
less toxins will lower health risks.

This presentation encapsulates Brown & Williamson’s promotional positioning of Advance cigarettes, including the express limits on the claims made. Thus, Advance is claimed to provide “All of the taste . . . Less of the toxins.”⁸ Immediately below this claim, the “less of the toxins” claim is amplified by the phrase “Reduced levels of toxins compared to the leading lights brand styles.” Directly above the promotional claim appears the statement, “There is no such thing as a safe cigarette.” Immediately below the promotional claim appears the boxed statement, “There is not enough medical information to know if Advance with less toxins will

⁶ This terminology was developed by Star Scientific, Inc., which had a role in developing Advance cigarettes and has itself test marketed Advance cigarettes using that company’s packaging. Brown & Williamson understands that Star Scientific has no current intention to market Advance cigarettes in the future.

⁷ Complete copies of the onserts used by Brown & Williamson with the two Advance cigarettes brand styles appear in Exhibit 3.

⁸ That key promotional language is claimed as a trademark by Brown & Williamson.

lower health risks.”⁹ These limiting statements appear clearly and conspicuously in all point-of-purchase displays¹⁰ and print advertisements¹¹ which contain lower-in-toxins claims.

B. Why Advance Is Lower In Toxins

The full Advance package onsert, which can be viewed when the clear plastic wrap is removed from the package, provides detailed information about the toxins reduced and how that is accomplished in Advance cigarettes. It explains that Advance cigarettes “combine two important new technologies to deliver rich tobacco taste and reduce the levels of many toxins.” These technologies are the Brown & Williamson Trionic™ filter and a tobacco curing process, patented by Star Scientific, Inc., that inhibits the formation of tobacco-specific nitrosamines (TSNAs), a group of toxins in tobacco and tobacco smoke.

The Trionic filter has three segments.¹² The first segment consists of an Ion Exchange Resin, the second consists of a special carbon, and the third is made of cellulose acetate, the substance found in most traditional cigarette filters. The three segments of the Trionic filter interact with different groups of toxic constituents in cigarette smoke. Smoke released from burning tobacco first moves through the filter segment containing the Ion Exchange Resin. This material interacts primarily with the semi-volatile constituents of tobacco smoke,¹³ particularly a group of compounds called aldehydes (including formaldehyde) and others like hydrogen

⁹ The Petition (at p. 6) asserts that, “In the minds of consumers, the disclaimer will not prevent the product as being perceived as less of a health risk.” Petitioners, however, present no evidence that consumers ignore this statement or fail to comprehend its plain meaning.

¹⁰ Pictures of the test market point-of-purchase displays and their copy appear in Exhibit 4.

¹¹ Representative print advertising copy used in the test market appears in Exhibit 2.

¹² The Trionic filter is pictured in Exhibit 5.

¹³ The various constituents in tobacco smoke occur in three forms: particles (which taken together, make up what is commonly known as ‘tar’); gases (which taken together, make up what is known as the vapor phase of cigarette smoke), and semi-volatiles (which can exist both as gases and particles).

cyanide. Some of these materials are trapped within the first segment, reducing their levels as the smoke continues through the filter.

Smoke next moves into the filter segment containing specialty carbon. This material adsorbs both semi-volatile constituents and gases. It continues to adsorb the aldehydes from the smoke, as well as trapping other constituents like benzene and acrolein. The smoke then moves through the last filter segment, consisting of cellulose acetate. This traditional filter material reduces the particles or tar levels of the smoke. The result of smoke passing through the three-stage Trionic filter is a significant reduction in many of the toxins, as compared to the levels found in smoke delivered by the leading lights cigarette brands.

Second, Advance cigarettes include flue-cured tobacco that is cured using a new patented process of Star Scientific, Inc. This reduces tobacco-specific nitrosamines (TSNAs), which have been difficult to avoid in cigarette smoke.¹⁴ This new curing process uses a combination of high-temperature and high-speed airflow that inhibits the formation of TSNAs, some of which are categorized as carcinogens by the International Agency for Research on Cancer. Advance cigarettes also contain oriental and burley tobaccos that are naturally low in TSNAs.

C. The Nature and Extent of Advance Toxin Reduction

The combination of these technologies reduces substantially a large number of cigarette smoke toxins. The Advance onsert discloses whether there are reductions and, if so, the percentage reduction in Advance smoke as compared to smoke from other leading light brands of each specified form. These presentations are shown as to 42 specific smoke constituents

¹⁴ TSNAs are formed during the curing stage of tobacco, when the leaves turn from a fresh green to a soft yellow. If the curing process is stopped short, TSNA formation is inhibited, but the tobacco is not aged sufficiently to provide satisfying taste. Allow the process to proceed for maximum flavor, on the other hand, and TSNAs will form in their usual amounts.

specified for disclosure in regulations proposed by the Massachusetts Department of Health.¹⁵

As the onsert shows,¹⁶ Advance cigarettes are lower in 32 of the 42 toxins, in amounts ranging from 14% to 81%, depending on the toxin.¹⁷ Thus, Advance cigarettes do provide less of a large number of toxins.¹⁸

III. ADVANCE CIGARETTES ARE NOT SUBJECT TO REGULATION AS “DRUGS” UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

The Petitioners request FDA to assert jurisdiction over Advance by embracing the now fully discredited proposition advanced by FDA for the first time in the mid-1990’s that cigarettes marketed for customary smoking use somehow are “New Drugs.” As demonstrated below, FDA should resist any temptation to go down that road again, because (i) the Supreme Court has definitively ruled that cigarette products without claims of “therapeutic benefit” are not subject to regulation by FDA; (ii) to the contrary, Congress has chosen to set policy for and regulate cigarettes without claims of “therapeutic benefit” under its tobacco-specific statutes; (iii) claims of reduced risk of a harm resulting from the use of a product -- be it cigarettes or automobiles or any other product -- do not bring that product within the FDCA, and (iv) any concerns that claims made for Advance may be false or misleading are, like any other consumer product, already subject to regulation and oversight of the Federal Trade Commission.

¹⁵ Thus, the toxins are ones which a leading public health agency believes not only could usefully be disclosed but whose disclosure should be compelled by law.

¹⁶ See Exhibit 3.

¹⁷ As to seven of the toxins, there is no significant difference between Advance and the compared brands. As to three of the toxins, there is no detectable level either in Advance or the compared brands.

¹⁸ The Petition does not present any evidence purporting to show that these reductions do not actually occur. It rather contends that the government should restrain cigarette manufacturers from claiming such reductions until the FDA has precleared the statement.

A. Advance Light Cigarettes Fall Directly Within FCLAA's Definition of "Cigarette."

In 1965, Congress first established its comprehensive program for the regulation of cigarettes by enacting the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331, *et seq.* Section 3 of FCLAA defines a "cigarette" as

(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 paragraph (A),

Identical definitions are used by the Internal Revenue Service for taxation purposes, 26 U.S.C. § 5702(b), and for identifying contraband cigarettes for law enforcement purposes, 18 U.S.C. § 2341(2).

Petitioners do not and cannot contend that Advance is anything but a cigarette. Advance is, in its simplest form, a roll of tobacco wrapped in paper with a filter attached. Its basic construction, manner of consumption and physical appearance are in every way identical to the hundreds of other cigarettes subject to the regulatory scheme defined by Congress. Advance cigarettes comply in all respects with the provisions of FCLAA and, as noted above, are regulated and taxed as cigarettes by BATF. As the Supreme Court has made clear, Congress has foreclosed FDA from unilaterally regulating or making policy decisions regarding smoking and health issues.

B. The Supreme Court Opinion In *FDA v. Brown & Williamson Tobacco Corporation* Bars FDA Regulation of All Tobacco Products Marketed -- As Is Advance -- Without Claims of Independent Therapeutic Benefit.

In *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120, 120 S. Ct. 1291 (2000), the United States Supreme Court made clear that the FDCA provides FDA with no authority over cigarettes and other tobacco products:

[W]e believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible.

529 U.S. at 126, 120 S. Ct. at 1297. The Court noted "Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a *distinct regulatory scheme* for cigarettes and smokeless tobacco." 529 U.S. at 155, 120 S. Ct. at 1312-13 (emphasis added). The Court specifically recognized FCLAA as the cornerstone of that regulatory regime, citing the stated intent of Congress to create "a comprehensive Federal program to deal with cigarette labeling and advertising with respect to smoking and health." 529 U.S. at 148, 120 S. Ct. at 1308 (citing 15 U.S.C. § 1331). In enacting FCLAA, the Court noted, Congress "enacted a statute reserving exclusive control . . . to itself" over cigarette labeling and advertising. *Id.* At 149, 120 S. Ct. at 1309. The Court further observed "Congress has persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health." 529 U.S. at 156, 120 S. Ct. at 1313 (emphasis in original).

Petitioners ask FDA to affirmatively try to evade the clear instruction of the Supreme Court decision by claiming that the opinion covers only "traditional tobacco products . . . as customarily marketed." *See, e.g.*, NCTFK Petition at 9. The term "traditional tobacco product" does not appear in the Court's Opinion. Rather, in *Brown & Williamson*, the Supreme Court

ruled the FDA had no jurisdiction over tobacco products “as customarily marketed.” *See, e.g.*, 529 U.S. at 156, 120 S. Ct. at 1313. In framing the issue in the case by reference to the FDA’s tobacco rulemaking, the Court specifically defined the scope of the term “as customarily marketed” to mean tobacco products marketed for smoking pleasure as opposed to those that make claims of therapeutic benefit to the user: “The FDA determined that cigarettes and smokeless tobacco are ‘drug delivery devices’ and therefore it had jurisdiction under the FDCA to regulate tobacco products as *customarily marketed* – that is, without manufacturer claims of *therapeutic benefit*.” 529 U.S. at 127, 120 S. Ct. at 1297-98 (emphasis added). And, it is that determination by FDA that the Supreme Court rejected.

In addition, both the decision below under review by the Court and the FDA’s own petition for *certiorari* make clear the scope of the term “customarily marketed.” In its decision declaring FDA’s assertion of jurisdiction over tobacco products beyond the Agency’s authority, the United States Court of Appeals for the Fourth Circuit explained:

Plaintiffs use the term “customarily marketed” in their briefs to indicate *tobacco products with customary claims such as smoking pleasure as opposed to tobacco products marketed with specific therapeutic claims such as weight loss*. Unless indicated otherwise, all references in this opinion are to tobacco products as customarily marketed.

Brown & Williamson Tobacco Corporation v. FDA, 153 F.3d 155, 161 n.9 (4th Cir. 1998) (emphasis added).

The FDA’s Petition for Writ of Certiorari seeking review of the Fourth Circuit decision similarly defined the scope of the issue it was asking the Supreme Court to rule on:

The court used the term “customarily marketed” to refer to *tobacco products marketed with claims concerning smoking pleasure and the like, rather than therapeutic claims, such as weight loss*. App 14a-15a n.9. The lower courts have sustained FDA’s authority to regulate cigarette products that are marketed with express claims of therapeutic value, and respondents concede that such authority exists. *See id.* at 80a n.3.

Petition for Writ of Certiorari, *FDA v. Brown & Williamson Tobacco Corporation*, No. 98-1152 at 12 n.3 (emphasis added).

In rejecting FDA's assertion of jurisdiction, the Court exhaustively reviewed the language of the FDCA and determined that FDA's mandate to ensure that marketed products are safe and effective for their intended use irreconcilably conflicted with the determination by FDA and others that tobacco products could not be found "safe" for any intended use. 529 U.S. at 134-37, 120 S. Ct. at 1301-03. The Court noted that

FDA may not . . . conclude that a drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market. Such regulation is incompatible with the FDCA's core objective of ensuring that every drug or device is safe and effective.

529 U.S. at 142, 120 S. Ct. at 1306. As such, the Court ruled that, "[c]onsidering the FDCA as a whole, it is clear that Congress intended to exclude tobacco products from the FDA's jurisdiction." *Id.*

The Court then reviewed the legislation, noted above, passed by Congress to specifically address the subject of tobacco and health and stated:

Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965. When Congress enacted these statutes, the adverse health consequences of tobacco use were well known, as were nicotine's pharmacological effects.

529 U.S. at 137-38, 120 S. Ct. at 1303-04 (citations omitted). The Court thus acknowledged the determination of Congress that issues related to smoking and health, including the regulation of and labeling claims, would remain the province of Congress.

Petitioners fail in their attempts to portray Advance as somehow different from other cigarettes "as customarily marketed." They do not and cannot take the product outside the scope of the Supreme Court ruling in *FDA v. Brown & Williamson*. As demonstrated below, the "reduced risk" claims that Petitioners attempt to construct for Advance are not within the ambit of therapeutic benefit claims that courts have found to be in FDA's purview. It is only when a

manufacturer makes claims that the tobacco product provides an independent therapeutic benefit to the health of consumers, such as those where FDA jurisdiction was upheld by courts prior to the Supreme Court ruling, that FDA may intervene.

C. Claims of Risk-Reduction Are Not Claims That Bring A Product Within FDA's Jurisdiction.

The crux of Petitioners' claims as to Brown & Williamson focuses on the statement "All of the taste . . . less of the toxins" and the discussion of the Trionic filter in connection with Advance. Petitioners apparently believe that any representation, express or implied, that smokers may be exposed to less toxic substances in Advance as compared to other cigarettes, regardless of the specific claim or how it is qualified or explained, will render the product a "drug" under the FDCA. If accepted, Petitioners' argument would impact a wide array of consumer products that are designed to reduce the risks inherent in the consumption or use of the product. For example, automobiles with improved safety features such as air bags, cleaning solutions designed to be less irritating or caustic to skin, low-lead gasoline designed to reduce air-borne contaminants, or chain-saws with anti-kickback protections would all potentially be subject to FDA preapproval. However, Petitioners' argument ignores FDA's history regarding risk reduction claims and the Supreme Court ruling in *Brown & Williamson*.

In that case, the Supreme Court based its decision that FDA had no authority over tobacco products, in part, on FDA's history of repudiation of authority over tobacco products, including FDA's disavowal of any authority over tobacco products with reduced-risk claims. Specifically, in 1979, FDA considered a Citizens Petition demanding that the Agency regulate both attached and detached cigarette filters as medical devices.¹⁹ Citizen Petition Nos. 77P-

¹⁹ While that letter addresses devices, the letter treated the issue of intended use under the "drug" definitions of the FDCA as identical to that under the "device" definition. Novitch/Goylan Letter at 3.

0185, 78P-0338. In a comprehensive analysis, FDA rejected the various grounds asserted as justifying its jurisdiction over cigarettes and detached filters. Letter from Mark Novitch for Jere E. Goylan, Commissioner of Food and Drugs, to John F. Banzhaf, III and Peter Georgiades (Nov. 25, 1980) (“Novitch/Goylan Letter”).²⁰

Specifically, the Agency rejected the argument that reducing the risk from use of an existing product brought the product within the FDCA. The Agency noted that

Many products are designed and sold to reduce the exposure of humans to hazardous substances. For example, catalytic converters and lead-free gasoline for use with automobiles are designed to reduce the exposure of humans to lead and hazardous by-products of gasoline combustion. These product, however, are not deemed to be within the Agency’s jurisdiction.

Id. at 11. The Agency further recognized the distinction between claims of positive therapeutic benefit versus claims of reduced risk of adverse effects:

Representations in cigarette labeling or advertising [cited in the Petition] as to the absolute or relative quantity of hazardous constituents of cigarette smoke or as to the safety of the cigarettes do not make the cigarettes or their filters intended for use in the mitigation, treatment or prevention of disease.

The representations in the filtered cigarette labeling and advertising [cited in the ASH Petition] are made in the context of long-standing public discussion of potential health hazards of smoking and, in recent years, of warnings which have been statutorily required on cigarette packaging [Petitioner] itself admits that the advertisements do not imply that there is a health benefit for which purpose the filter cigarette should be used, absent the desire to smoke [citations to petitions].

Where, as here, attached filters are at most represented as making the cigarettes to which they are attached less hazardous, neither the cigarettes themselves nor the filters are thereby intended for use in the mitigation, treatment or prevention of disease.

Novitch/Goyan Letter at 8 (emphasis added). The Supreme Court specifically cited the Novitch/Goyan letter as one of FDA’s representations upon which it relied in determining that FDA had no authority over tobacco products. 529 U.S. at 153, 120 S. Ct. at 1311.

²⁰ Attached as Exhibit.

This distinction between claims of lesser adverse effect or reduced-risk and claims of a positive therapeutic impact on disease states independent of the product at issue is well-grounded in the FDCA. First, the distinction flows naturally from the established premise that toxicity of a product alone is insufficient to qualify it as a “drug” under the FDCA. *National Nutritional Foods Ass’n v. Matthews*, 557 F.2d 557 F.2d 325, 334-36 (2d Cir. 1977). Further, FDA has recognized in other contexts that information or representations that a product does not contain, or contains a lesser amount of, a substance or compound associated with a deleterious health effect does not make the product a drug. Thus, foods may expressly claim to be hypoallergenic, 21 C.F.R. § 105.62, low in calories or containing reduced calories, 21 C.F.R. §§ 101.60, 105.66, low in sodium, 21 C.F.R. § 101.61, or low in fat or cholesterol, 21 C.F.R. § 101.62, without falling under FDA’s definition of “drug.”

Finally, the cases cited by the Petitioners (Petition at 9) as defining the “therapeutic claims” that would bring a tobacco product within FDA’s drug definition show that such claims must show intent to treat, mitigate or cure a disease state unrelated to the product. In *United States v. 46 Cartons . . . Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953), the court considered whether labeling which allegedly represented Fairfax cigarettes as

effective in preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), meningopneumonitis psittacosis. Libellant further contends that claimant represents that the smoking of these cigarettes is innocuous for persons suffering from circulatory diseases, high blood pressure and various heart conditions.

Id. at 337. The court ultimately held that, “[i]f 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 treatment of the various named diseases, claimant cannot now be heard to say that it is selling only cigarettes and not drugs.” *Id.* at 338. Thus, despite the defendant’s claim that the cigarettes were sold only

for smoking pleasure, the court relied on the defendant's express claims of treatment for disease states unrelated to smoking to determine that the product should be classified as a "drug."

Petitioners also cite to *United States v. 354 Cartons . . . Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959), in which the court considered the status of cigarettes to which tartaric acid had been added and which were represented in labeling and advertisements as effective for weight loss purposes. The manufacturer made clear through its labeling that the cigarettes were distributed for weight reduction purposes and not for tobacco enjoyment; the display card informed consumers "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. Based on the manufacturer's express representations in labeling and advertising, the court concluded that the manufacturer's "primary, if not the sole inducement intended . . . to the purchase and use of its product was the representation of the product's efficacy to reduce human avoirdupois." *Id.* at 852. As such, the court readily found the product to be a drug subject to FDCA requirements.

In a contemporaneous case, however, claims of reduced risk of adverse effect were clearly distinguished from the claims of positive therapeutic benefits at issue in the *Fairfax* and *Trim* cases. In *FTC v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573 (S.D.N.Y. 1952), *aff'd*, 203 F.2d 955 (2d Cir. 1953), the court addressed whether advertisements for Chesterfield cigarettes which were allegedly represented that Chesterfields could be smoked "by any smoker without inducing any adverse effect upon the nose, throat and accessory organs of the smoker" brought those tobacco products within the "drug" definition of section 15(c) of the Federal Trade Commission Act. That definition is identical to the definition of "drug" in the FDCA. The court clearly distinguished between claims that a product provides a positive therapeutic benefit

independent of the product and claims that a product contains less of or none of the adverse effects generally attributed to the product:

If [the FTC's] allegation were construed as a charge that the defendant affirmatively claimed a therapeutic purpose for Chesterfield cigarettes, we would be confronted with a question of fact that would have to await trial. But this is not the case here. It is true, that cigarettes have, in the past, been placed on the market and advertised as having therapeutic purposes. [citing *United States v. 46 Cartons . . . Fairfax Cigarettes*, discussed *supra*]. However, that is *toto caelo* from a representation by the defendant of a 'non-adverse' rather than a beneficial effect.

Id. at 575. The *Liggett* court went on to hold that such reduced-risk claims did not make the product into a drug.

Thus, the cases that define the scope of the exception to the Supreme Court ruling in *Brown & Williamson* make clear that, in order for a tobacco product to be a drug, its manufacturer or vendor must represent it as having a positive therapeutic benefit, and that a claim of lack of, or reduction of, the adverse effects or consequences of smoking does not constitute a drug claim. Plaintiffs' attempt to sidestep that ruling must be denied.

IV. INTERPRETATION AND REGULATION OF CIGARETTE ADVERTISING CLAIMS ARE THE PROVINCE OF THE FEDERAL TRADE COMMISSION, NOT FDA.

Petitioners theorize that, absent FDA intervention, consumers may be misled by claims made in Advance advertising. However, as part of its strategy for the regulation of cigarettes, Congress has vested the responsibility for ensuring that the claims made for cigarettes are truthful and nonmisleading in the Federal Trade Commission, not the FDA. 15 U.S.C. § 1336. FTC has in the past taken strong enforcement action against manufacturers it believed were making false or misleading claims as to the possible reduction in risk from tobacco products were being made. *See, e.g., R.J. Reynolds Co.*, FTC Docket No. C-3892 (August 16, 1999), *Santa Fe Natural Tobacco Co.*, FTC Docket No. C-3952 (June 12, 2000) (Consent Orders prohibiting advertisements promoting cigarettes as having "no additives" without clear and

conspicuous disclaimers based on allegation that the advertisements at issue falsely claimed that Winston and Santa Fe cigarettes, respectively, were safer than other cigarettes); *American Tobacco Co.*, FTC Docket No. C-3547 (Jan. 3, 1994) (Consent Order prohibiting certain claims relating to the relative amount of tar that smokers of Carlton cigarettes would take in).

The FTC has historically determined whether advertising claims are substantiated by adequate evidence. In the case of tobacco products, it has at times sought assistance from other Federal agencies on the scientific issues posited, just as the FTC has done in cases involving countless other products raising scientific issues. *See, e.g.*, HHS National Institutes of Health, National Cancer Institute, Monograph 13: Risks Associated with Smoking Cigarettes With Low Machine-Measured Yields of Tar and Nicotine (November 2001). In fact, Petitioners themselves concede that, assuming FDA could legally assert jurisdiction over Advance, it would still need to “promptly define and articulate a consistent and scientifically rigorous approach” to regulate such products. Petition at 15. The clear conflict between the FDCA and the regulation of tobacco products demonstrated by the *Brown & Williamson* Court makes readily apparent why FDA has no protocol for evaluating such products readily available – their regulation is beyond the scope of the Agency’s mandate from Congress.

Finally, we note that FDA’s assertion of jurisdiction over Advance or other tobacco products based upon its unilateral interpretation of the claims made in connection with the product could potentially raise First Amendment questions. In recent years, numerous courts have taken FDA to task for making regulation a *quid pro quo* for allowing manufacturers of products *clearly within the Agency’s jurisdiction* to exercise their right to engage in truthful, non-misleading commercial speech. For example, the Supreme Court recently rejected as unconstitutional a provision of FDAMA that required pharmacists who compound drugs to

forego their right to advertise particular compounded products in exchange for not being subject to the Agency's new drug pre-approval requirements. *Thompson v. Western States Medical Center*, No. 01-344 (April 29, 2002). The United States Court of Appeals for the District of Columbia found FDA's regulation of "health claims" for dietary supplements inconsistent with the First Amendment because the agency had refused to consider appropriate disclaimers and qualifications for claims that the Agency did not believe had been sufficiently proven by the manufacturer. *Pearson v. Shalala*, 164 F.3d 650, 659 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999). *See also Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 67 (D.D.C. 1998) (noting that FDA "exaggerates its overall place in the universe" in asserting that any scientific claims regarding safety or effectiveness are presumptively misleading unless and until validated by the Agency), *vacated and remanded on other grounds*, 202 F.3d 331 (D.C. Cir. 2000).

Given the extensive language explaining and qualifying the scope of the claims actually made by Brown & Williamson for Advance, the Agency's experience in these recent cases would appear particularly instructive. In fact, FDA itself has turned to the public for comment and guidance on how it should regulate products under its mandate in a manner consistent with the First Amendment. 67 Fed. Reg. 34,942 (May 16, 2002). Given the Agency's current uncertainty as to the scope of its authority over commercial speech in light of the First Amendment for products clearly within its jurisdiction, embarking on the speech-based regulation of products specifically ruled to be beyond its reach does not appear to be an appropriate use of Agency resources.

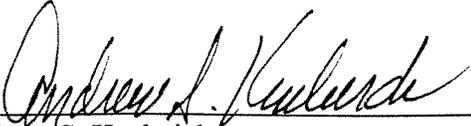
V. CONCLUSION

For the reasons stated above, The Agency does not have jurisdiction over Advance cigarettes.

FDA should therefore deny the petitions.

Respectfully submitted,

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