IN THE FOOD AND DRUG ADMINISTRATION

Petition for Regulation of Ariva™	)	Docket Nos.: 01P-0572 & 02P-0075

STAR SCIENTIFIC, INC.'S RESPONSE TO THE COMMENTS OF GLAXOSMITHKLINE CONSUMER HEALTHCARE, LP

CHARLES FRIED
1545 Massachusetts Avenue
Cambridge, Massachusetts 02138
Telephone: (617) 495-4636
Facsimile: (617) 496-4865

OF COUNSEL:

Kathleen Moriarty Mueller, Esquire
McSweeney & Crump, P.C.
11 South Twelfth Street
Richmond, VA 23218
(804) 783-6800

David L. Rosen, Esquire
McDermott, Will & Emery
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8075

R. Bruce Dickson, Esquire
Paul, Hastings, Janofsky & Walker LLP
1299 Pennsylvania Avenue, NW, Tenth Floor
Washington, D.C. 20004-2400
(202) 508-9500

Michael F. Cole, Esquire
Bergeson & Campbell, P.C.
1203 19th Street, N.W., Suite 300
Washington, D.C. 20036-2401
(202) 962-8585

Although Petitioner GlaxoSmithKline Consumer Healthcare, LP has filed a lengthy response to Star Scientific's May 1, 2002 Comments on its Petition to regulate Ariva™ as a "food" under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.*, Petitioner cannot alter the fact that Ariva™ is a compressed form of Star Scientific's Stonewall™ dry snuff that is used for tobacco satisfaction, manufactured under a license from the Bureau of Alcohol, Tobacco and Firearms (BATF), taxed as a "snuff" under federal excise laws, 26 U.S.C. § 5701, *et seq.*, and subject to the warning requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), 15 U.S.C. §§ 4401-4408. Thus, as we explained in detail in our prior Comments, Ariva™ is not a "food" within the meaning of the FDCA, and, under the Supreme Court's decision in *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), FDA lacks jurisdiction to regulate Ariva.™ None of Petitioner's counter-arguments are valid.

1. Petitioner first chides us for citing *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983), for the proposition that Ariva is not a food because Ariva is not used "primarily for taste, aroma or nutritive value." (Pet. July 11 Comments at 2). That criticism is unwarranted, because FDA also uses the *Nutrilab* analysis. For example, FDA recently determined that

neither "Nicotine Water" (a product containing water and pharmaceutical grade nicotine) nor its nicotine ingredients are "foods" because "they are not being consumed for their taste, aroma, or nutritive value."[1] That analysis applies to Ariva as well. As we explained in our previous Comments, people do not consume Ariva for its taste, aroma or nutritive value. They consume Ariva for the same reason they consume other tobacco products: because they like the tobacco satisfaction it provides.[2]

2. Noting that courts have also considered whether a product is sold in food form or used for food, Petitioner next claims that Ariva is a "candy-like product" that is analogous to the "Masterpiece Tobacs" gum, because, in Petitioner's view, Ariva has the appearance of candy, is sold in food form, and contains "standard constituents of food," such as polymers, buffering agents, sweeteners and flavorings. (Pet. July 11 Comments at 2-4 & n. 7). Petitioner is incorrect. As we explained in our prior Comments, Ariva is not a "food" under this analysis because it is not sold in food form, it is not

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[1] Letter from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, to William B. Schultz, at 4, n.3 (July 1, 2002) (citing *Nutrilab* v. *Schweiker*, *supra*).

[2] Star Scientific's May 1, 2002 Comments in Docket No. 02P-0075, at 6-8.

similar in taste or appearance to candy, and it is not used for food.[3] Petitioner continues to mischaracterize Ariva as a candy-like product because it cannot refute that Ariva is a compressed form of Stonewall dry snuff that is used for tobacco satisfaction as are other tobacco products.

For example, Petitioner asserts that Ariva has a "smooth, brown, edible outer coating that appears in the color of chocolate." (Pet. July 11 Comments at 4). That assertion is both incorrect and misleading, because it suggests that Ariva has a chocolate or candy outer coating. It does not. As we explained in our prior Comments, Ariva is simply a compressed version of Star Scientific's Stonewall dry snuff; it has no additional coating, candy or otherwise.[4] Accordingly, if an Ariva cigalett™ is crushed, it produces exactly the same product as Stonewall dry snuff, and the crushed Ariva cigalett has exactly the same appearance, color and graininess throughout.

Likewise, Petitioner's alleged chemical analysis does not demonstrate that Ariva is a "food," because the ingredients cited by Petitioner are not unique to food, but are commonly found in tobacco products as well. Indeed, Petitioner's chemical analysis reveals that there are also polymers

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[3] See Star Scientific's May 1, 2002 Comments in No. 02P-0075, at 7-10; Star Scientific's May 1, 2002 Comments in No. 01P-0572, at 20-22.

[4] See Star Scientific's May 1, 2002 Comments in No. 02P-0075 at 2-3 & 7-8; Star Scientific's May 1, 2002 Comments in No. 01P-0572, at 3 & 20.

and buffering agents in cigarettes, and that cigarettes contain a higher level of some sugars (specifically, fructose and sucrose) than Ariva does.[5] Furthermore, flavorings similar to those in Ariva are commonly found in other smokeless tobacco products.[6]

Thus, contrary to Petitioner's assertion, Ariva is not "sold in food form." (Pet. July 11 Comments at 5). Ariva is a smokeless tobacco product that contains ingredients that are commonly found in other tobacco products; it is marketed and sold as a tobacco product; and it is used to provide tobacco satisfaction, as are other tobacco products. *Brown & Williamson* therefore precludes FDA from exercising jurisdiction over Ariva.

3. None of Petitioner's attempts to distinguish *Brown & Williamson* are persuasive. Petitioner first claims that although a food is "deemed to be adulterated" if it contains "any food additive which is unsafe . . . ," 21 U.S.C. § 342(a)(2)(A), the term "safety" means something less in the food additive provisions of the FDCA than it does in the drug provisions at issue in *Brown & Williamson*. To support this assertion, Petitioner states that

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[5] See Analysis of Chemical Constituents and Physical Properties of Ariva, at 2-4, attached to April 26, 2002 Comments of GlaxoSmitherKine Consumer Healthcare, LP.

[6] See Star Scientific's May 1, 2002 Comments in No. 02P-0075, at 13-15; Star Scientific's May 1, 2002 Comments in No. 01P-0572, at 11-12.

FDA has "broad authority" to prescribe "the maximum quantity of the additive that may be used" and to impose "any labeling requirements deemed necessary to assure the safety of an additive." (Pet. July 11 Comments at 6, citing 21 U.S.C. § 348(c)(1)). Therefore, Petitioner maintains, *Brown & Williamson* is distinguishable, because FDA could allow Ariva to be marketed under certain conditions. (Pet. July 11 Comments at 9). Petitioner is mistaken.

Petitioner's reliance on FDA's authority to impose labeling requirements on food additives is misplaced because, as Petitioner acknowledges (July 11, 2002 Comments at 6 & n.12), the CSTHEA specifically prohibits "any Federal agency" from requiring any "statement relating to the use of smokeless tobacco products and health, other than the statements required by [the CSTHEA]". 15 U.S.C. § 4406(a). Thus, as the Supreme Court explained in *Brown & Williamson*, 529 U.S. at 154, "Congress reserved for itself an aspect of smokeless tobacco regulation that is particularly important to the FDCA's regulatory scheme."

Moreover, although Petitioner hypothesizes that FDA might possibly be able to approve the use of tobacco as a food additive in Ariva under certain conditions, it does not deny that FDA has the authority to ban the sale of Ariva if it determines that the tobacco in Ariva is a "food additive

which is unsafe within the meaning of Section 409." 21 U.S.C. § 342(a)(2)(A). That was the same authority FDA claimed to have in *Brown & Williamson*, 529 U.S. at 159, where the agency contended that "it would have the authority to ban cigarettes and smokeless tobacco products entirely" if it were to determine that they provide "no reasonable assurance of safety." The Supreme Court disagreed, holding that FDA does not have that authority:

> Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in this area. Given this history and the breadth of the authority that the FDA has asserted, we are obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power.

Id. at 159-160.

4. Petitioner next suggests that this holding is inapplicable to Ariva because Star Scientific has claimed that Ariva is "'safer' than the traditional tobacco products at issue in *Brown & Williamson*." (Pet. July 11, 2002 Comments at 7). Petitioner is mistaken on several counts, both factual and legal.

As a matter of fact, Star Scientific has *not* claimed that Ariva is safer than other tobacco products.[7] Instead, the company has repeatedly stated that "there is no proof that reducing the TSNAs in Ariva™ will lead to a reduction in the health risk associated with its use,"[8] and has acknowledged that additional studies need to be done to determine whether TSNA reductions in smokeless tobacco reduces the risk of oral cancer.[9]

As a matter of law, the Court in *Brown & Williamson* did *not* limit its holding to what Petitioner deems to be "traditional tobacco products."[10] Instead, the Court held that "Congress' tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed" (529 U.S. at 156) – that is, "without manufacturer claims of therapeutic benefit." *Id.* at 127. As we explained in our prior Comments, Ariva falls within that

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[7] See Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572, at 15-18 & n.25.

[8] "TOBACCO SPECIFIC NITROSAMINES," a Fact Sheet for Distribution to Public Health Colleagues (Attachment 9 to Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572).

[9] See, *e.g.*, "QUESTIONS AND ANSWERS," a Fact Sheet for Distribution to Public Health Colleagues, at 1 (Attachment 3 to Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572).

[10] See Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572, at 12-14; Star Scientific's May 1, 2002 Comments in Docket No. 02P-0075, at 16-17.

holding, because it is a "smokeless tobacco" product within the meaning of the CSTHEA, and Star Scientific does not make any claims of therapeutic benefit for Ariva.[11]

5. Petitioner does not dispute that Ariva contains "ground, powdered . . . tobacco" as required by the CSTHEA, 15 U.S.C. § 4408(1). Instead, Petitioner claims that Ariva is not a "smokeless tobacco product" because the tobacco in Ariva "has been hardened" or "compressed." (Pet. July 11 Comments at 10). That fact is irrelevant, for nothing in the statutory definition suggests that "ground, powdered . . . tobacco that is intended to be placed in the oral cavity" (15 U.S.C. § 4408(1)) suddenly ceases to be a "smokeless tobacco" product simply because it is hardened or compressed into a pellet (which Star Scientific calls a "cigalett"™). Indeed, Petitioner implicitly recognizes this by conceding that "hardened blocks or ropes of tobacco" *are* "smokeless tobacco products" within the meaning of the CSTHEA. (Pet. July 11, 2002 Comments at 10). Petitioner does not (and cannot) explain why tobacco that has been "hardened" into a "block" or "rope" is a "smokeless tobacco product," while Ariva, which contains ground, powdered tobacco that has been hardened into a "cigalett™", is not.

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[11] See Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572, at 10-12 & 15-18 (emphasis in original).

As we explained in our previous Comments, *all* of these products meet the statutory definition of "smokeless tobacco."[12]

Petitioner also says that Ariva is not "intended to be placed in the oral cavity" because it is "designed to be ingested through the saliva created by working the product in one's mouth." (Pet. July 11 Comments at 10). We are uncertain of the meaning of this comment. The Ariva package provides the following instructions: "Place a Cigalett™ piece in mouth and allow to dissolve. **Do not** chew or swallow whole."[13] To the extent that Petitioner is suggesting that Ariva is intended to be used in some other manner, Petitioner is incorrect. Similarly, if Petitioner means to suggest that Ariva is not a "smokeless tobacco" product because expectoration is not required, that suggestion is equally incorrect. As we explained in our prior Comments, the CSTHEA does not make expectoration a defining attribute of a "smokeless tobacco" product, and there were smokeless tobacco products on the market

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[12] See Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572, at 10-12; Star Scientific's May 1, 2002 Comments in Docket No. 02P-0075, at 13-15.

[13] See Exhibit 5 to Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572; Exhibit 4 to Star Scientific's May 1, 2002 Comments in Docket No. 02P-0075.

before the introduction of Ariva that dissolved in the mouth and did not require expectoration.[14]

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For these reasons, as well as for those stated in our previous Comments, the Petitions to regulate Ariva as a "food" or "drug" within the meaning of the FDCA should be denied.

Respectfully Submitted,

Charles Fried by Kathleen M Mueller

CHARLES FRIED
1545 Massachusetts Avenue
Cambridge, Massachusetts 02138
Telephone: (617) 495-4636
Facsimile: (617) 496-4865

OF COUNSEL:

Kathleen Moriarty Mueller, Esquire
McSweeney & Crump, P.C.
11 South Twelfth Street
Richmond, VA 23218
(804) 783-6800

David L. Rosen, Esquire
McDermott, Will & Emery
600 13th Street, N.W.
Washington, D.C. 20005-3096
(202) 756-8075

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[14] See Star Scientific's May 1, 2002 Comments in Docket No. 01P-0572, at 10-12; Star Scientific's May 1, 2002 Comments in Docket No. 02P-0075, at 13-15.

R. Bruce Dickson, Esquire
Paul, Hastings Janofsky & Walker LLP
1299 Pennsylvania Avenue, NW, Tenth Floor
Washington, D.C. 20004-2400
(202) 508-9500

Michael F. Cole, Esquire
Bergeson & Campbell, P.C.
1203 19th Street, N.W., Suite 300
Washington, D.C. 20036-2401
(202) 962-8585