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MCDERMOTT, WILL & EMERY

October 23, 2002

VIA HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

Re: Star Scientific, Inc.'s Filing of Response to Comments
Concerning Citizen Petitions, Docket Nos. 01P-0572 and 02P-0075

Dear Sir/Madam:

On behalf of our client, Star Scientific, Inc. attached please find the response to comments filed on October 1, 2002, by Ropes & Gray on behalf of GlaxoSmithKline Consumer Health Care LP, on the Citizen Petitions referenced above concerning Star Scientific's compressed powdered hard tobacco product, Ariva™ Cigalett™ pieces. The comments offer no new, substantive information and merely restate the Petitioner's views that Star has previously addressed.

As you know, Ariva™ is a compressed form of Star Scientific's Stonewall™ dry snuff and both products are used for tobacco satisfaction, manufactured under a license from the Bureau of Alcohol, Tobacco and Firearms, taxed as a "snuff" under federal excise laws, and subject to the warning requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986. Ariva™ is not a "food" within the meaning of the Federal Food, Drug and Cosmetic Act.

We maintain the firm belief that Star Scientific's compressed powdered hard tobacco product Ariva™ falls outside of FDA's jurisdiction, pursuant to the Supreme Court decision in FDA v. Brown & Williamson Tobacco Corporation, 529 U.S. 120 (2000), and that the Petitions are without merit and should be denied.

Sincerely yours,

02P-0075 RC 5

David L. Rosen

cc: Charles Fried, Esq.

Paul L. Perito, Esq.
Chairman, President and COO
Star Scientific, Inc.

Robert E. Pokusa, Esq.
General Counsel
Star Scientific, Inc.

IN THE FOOD AND DRUG ADMINISTRATION

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

STAR SCIENTIFIC, INC.'S RESPONSE TO THE OCTOBER 1, 2002 COMMENTS OF GLAXOSMITHKLINE CONSUMER HEALTHCARE, LP

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Apparently not satisfied with the arguments made in its Petition to regulate Ariva™, and its two subsequent sets of comments, Petitioner GlaxoSmithKline Consumer Healthcare, LP filed another lengthy set of comments on October 1, 2002 in an attempt to demonstrate that FDA has jurisdiction to regulate Ariva™ as a "food" under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* Petitioner's latest comments largely repeat its prior comments, and they are no more persuasive the second or third time around. Thus instead of cluttering the record, we will limit this response to Petitioner's new arguments and will simply note that our prior Comments (dated May 1, 2002, July 22, 2002, and August 16, 2002) refute Petitioner's old arguments and conclusively demonstrate that (1) Ariva™ is not a "food" within the meaning of the FDCA; and (2) under *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), FDA lacks jurisdiction to regulate Ariva.™

1. Petitioner spends several pages attempting to shoot down an argument that Star Scientific never made – namely, that *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335 (7th Cir. 1983), and not *United States* v. *Technical Egg Products, Inc.*, 171 F. Supp. 326 (N.D. Ga. 1959), and the factors cited by FDA in the Masterpiece Tobacs case, provides the controlling definition of what constitutes a "food" under the FDCA. (Petitioner's October 1, 2002

Comments at 4-7). As an initial matter, we do not perceive there to be any inconsistency between these cases. Indeed, the *Nutrilab* court cites *Technical Egg Products*. See 713 F.2d at 337.[1] Moreover, our previous comments demonstrate that Ariva is distinguishable from Masterpieces Tobacs and is not a "food" because it is neither consumed "primarily for taste, aroma or nutritive value" (*Nutrilab*, 713 F.2d at 337), nor sold in food form or generally regarded as a food (*Technical Egg Products*, 171 F. Supp. at 328).[2] Instead, Ariva is a "smokeless tobacco" product within the meaning of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA); it contains ingredients that are commonly found in other

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[1] Petitioner also asserts that *Nutrilab* involved the definition of the term "drug" in 21 U.S.C. § 321(g)(1)(c), rather than the definition of "food" in section 321(f). (Petitioner's October 1, 2002 Comments at 5-6). Petitioner apparently overlooked the portion of the opinion in which the Seventh Circuit stated that

> the statutory definition of "food" . . . includes in Section 321(f) the common-sense definition of food. When the statute defines "food" as "articles used for food," it means that the statutory definition of "food" includes articles used by people in the ordinary way most people use food – primarily for taste, aroma, or nutritive value.

Nutrilab, 713 F.2d at 337.

[2] See Star Scientific, Inc. Comments on Citizen Petition for Regulation of Ariva™, Docket No. 02P-0075 (May 1, 2002), at 6-10; Star Scientific's Response to the Comments of GlaxoSmithKline Consumer Healthcare, LP, Docket Nos. 01P-0572 & 02P-0075 (August 16, 2002), at 1-4.

tobacco products; it is marketed, sold and regulated as a tobacco product; and it is used to provide tobacco satisfaction, as are other tobacco products.

Petitioner's latest attempt to refute this argument focuses on the fact that Star Scientific has made statements to the effect that adult smokers may use Ariva "to get tobacco taste and satisfaction when they cannot smoke." (Petitioner's October 1 Comments at 3 (quoting a Star Scientific press release, with emphasis added by Petitioner)). But as we explained in our prior Comments, that fact does not distinguish Ariva from other tobacco products such as cigarettes, snuff and chewing tobacco, which are clearly not food even though they are used for the tobacco taste and satisfaction they provide.[3]

2. Perhaps recognizing the weakness of its prior argument that Ariva is not a "smokeless tobacco" product within the meaning of the CSTHEA, Petitioner now maintains that the question whether Ariva is subject to the CSTHEA is irrelevant to the question whether FDA may regulate Ariva as a "food." (Petitioner's October 1, 2002 Comments at 17-21). Petitioner is mistaken. In *FDA* v. *Brown & Williamson Tobacco, Inc.*, the Supreme Court specifically relied on the fact that Congress has enacted several statutes, including the CSTHEA, that address "the particular subject of

[3] See Star Scientific's May 1 Comments at 7.

tobacco and health." 529 U.S. 120, 155 (2000). These "tobacco-specific statutes," the Court held, create a "distinct regulatory scheme for cigarettes and smokeless tobacco" and "preclude the FDA from regulating tobacco products as customarily marketed." *Id.*

As we explained in our previous Comments, Ariva is a "smokeless tobacco" as defined in both the CSTHEA and the federal excise tax and licensing provisions of the Internal Revenue Code.[4] It is, therefore, outside the scope of FDA's jurisdiction as construed by the Supreme Court in *Brown & Williamson*.

The fact that Star Scientific believes Ariva to be an "innovative smokeless tobacco product" does not alter this conclusion. (Petitioner's October 1, 2002 Comments at 19 (internal quotations omitted)). As we have previously explained, *Brown & Williamson* is not limited to what Petitioner describes as "traditional" or "conventional" tobacco products.[5] Indeed, those terms are not found in either the *Brown & Williamson* decision or the CSTHEA.

3. Finally, Petitioner's concerns about Internet sales of Ariva are misplaced. Star Scientific, with some success, has attempted to dissuade the

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[4] See, *e.g.*, May 1, 2002 Comments at 1-10.

[5] See May 1, 2002 Comments at 15-17; August 16, 2002 Comments at 7-8.

few Internet retailers selling Ariva from continuing the practice. In spite of these efforts, Petitioner cites four instances in which its outside counsel purchased Ariva from an Internet retailer. While the retailer required a credit card for these purchases, Petitioner alleges that no further proof that the purchaser was at least 18 years old was demanded. (Petitioner's October 1, 2002 Comments at 21-23). Star Scientific opposes any form of tobacco sales to minors and regards this as a serious issue. However, the isolated instances cited by Petitioner do not "raise especially significant concerns," as Petitioner suggests. (Petitioner's October 1, 2002 Comments at 23).

Moreover, *Brown & Williamson* precludes FDA from regulating the sale of tobacco products as customarily marketed. Although Star Scientific supports legislative efforts to give FDA this authority, Congress has not yet acted. Until Congress changes the law, FDA lacks jurisdiction to regulate Ariva.

* * * *

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,

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