IN THE FOOD AND DRUG ADMINISTRATION

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

STAR SCIENTIFIC, INC.'S RESPONSE TO THE NOVEMBER 14, 2002 AND NOVEMBER 26, 2002 COMMENTS OF GLAXOSMITHKLINE CONSUMER HEALTHCARE, LP

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In filings dated November 14 and November 26, 2002, Petitioner GlaxoSmithKline Consumer Healthcare, LP supplemented the record with allegedly new information about the chemical composition and sale of Ariva.™ Petitioner maintains that this information supports its contention that FDA has jurisdiction to regulate Ariva™ as a "food" or "drug" under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* Petitioner is mistaken. Nothing in Petitioner's supplemental filings alters the facts that (1) Ariva™ is not a "food" or "drug" 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 has supplemented the record with a new chemical analysis that purportedly shows that Ariva has been "reformulated" so that each cigalett™ is "slightly smaller and harder," has a "more intense mint flavor" and "delivers nicotine in an even more efficient manner."[1] Petitioner's November 14, 2002 Comments, at 1. Even if one assumes, for purposes of argument, that Petitioner's chemical analysis is accurate, it is irrelevant to the question whether Ariva is a "food" subject to regulation by FDA or a smokeless tobacco product that is outside FDA's jurisdiction.

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[1] On the other hand, the "reformulated" Ariva supposedly has less sugar and the same amount of nicotine as were purportedly found in an earlier batch. Attachment A to Petitioner's November 14, 2002 Comments, at 4.

Petitioner did not offer any analysis of admitted smokeless tobacco products, such as Star's Stonewall™ moist snuff. Thus, Petitioner's chemical analysis of Ariva (impressive looking though it may be) says nothing about whether Ariva differs from other smokeless tobacco products. It makes about as much noise as one hand clapping.[2]

[2] Petitioner states that Ariva™ has a pH of 8.4 (Lot 102) and 8.6 (Lot 110). Petitioner asserts that these are high pH levels that "allow[] for optimal absorption of nicotine." (Petitioner's November 14, 2002 Comments, Attachment A, at 2). Neither we nor any other independent laboratory that has tested Ariva™ has obtained these types of results. After the latest submission by Petitioner, we tested retained samples at Star's laboratory of lots 102 and 110 under the Star Lab method, using the CDC method, using artificial saliva (Salivart), and using human saliva, in order to attempt to replicate Petitioner's reported pH levels. The results all showed pH levels between 7.08 and 7.44.

Sample	Container ID	2g Ariva in 20 mL HPLC Water (Star Lab method)	2g Ariva in 10 mL HPLC Water (CDC method)	1 Ariva in 10 mL Artificial Saliva (Salivart, pH=6.2)	1 Ariva in 10 mL Human Saliva – collected from WZH, pH = 7.0)
Ariva™ Control 000102	000102	7.44	7.29	7.36 Weight of Ariva 0.26g	7.14 Weight of Ariva 0.27g
Ariva™ Control 000110	000110	7.38	7.21	7.36 Weight of Ariva 0.22g	7.08 Weight of Ariva 0.25g

For comparison purposes, we also tested Skoal Long Cut Wintergreen moist snuff and Copenhagen moist snuff. We found that these smokeless products registered pH levels between 7.64 and 7.79, which is higher than the pH levels found in the Ariva samples.

Sample	Container ID	2g moist snuff in 20 mL HPLC Water (Star Lab method)	2g moist snuff in 10 mL HPLC Water (CDC method)
Skoal Long Cut Wintergreen Snuff	52/2KH;S2ENVII	7.64	7.65
Copenhagen Snuff	2NCIVVQ; Made Dec 16, 2002K K	7.78	7.79

Moreover, as we explained in our previous comments, a wide variety of flavorings, including mint, are commonly added to tobacco products.[3] Therefore, the fact that Ariva contains mint neither distinguishes it from other tobacco products nor demonstrates that it is a "food."

2. Petitioner's allegation that Ariva was designed to deliver nicotine efficiently similarly provides no grounds for FDA jurisdiction. Indeed, FDA previously attempted to regulate cigarettes as drugs in part because the agency found that cigarette manufacturers "'designed' cigarettes to provide pharmacologically active doses of nicotine to consumers." *FDA* v. *Brown & Williamson*, 529 U.S. 120, 127 (2000) (quoting 61 Fed. Reg. at 44849). Nevertheless, the Supreme Court invalidated the FDA regulations, holding that "Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products." *Brown & Williamson*, 529 U.S. at 126. As we have explained in detail in our prior Comments, that holding is controlling in this case, because Ariva is a smokeless tobacco product within the meaning of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), one of the tobacco-specific statutes on which the *Brown &*

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[3] 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, Star Scientific's August 16, 2002 Comments in Nos. 01P-0572 and 02P-0075, at 3-4.

Williamson Court relied, and the Bureau of Alcohol, Tobacco and Firearms ("BATF") has classified Ariva as a snuff tobacco subject to federal taxation and the regulations applicable to smokeless tobacco products.[4]

As it has in the past, Petitioner continues to attempt to distinguish *Brown & Williamson* by referring to evidence that Ariva is not like "conventional" smokeless tobacco products. Petitioner's November 26, 2002 Comments at 2. This latest attempt is no more successful than were its predecessors, because the relevant question under *Brown & Williamson* is not whether Ariva is a "conventional" smokeless tobacco product, but whether Ariva is a "smokeless tobacco" within the meaning of the CSTHEA.[5] As our prior Comments have shown, Ariva is a "smokeless tobacco" under the CSTHEA because it is a "finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. §

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[4] See See Star Scientific's May 1, 2002 Comments in No. 02P-0075, at 10-19; Star Scientific's May 1, 2002 Comments in No. 01P-0572, at 7-15, Star Scientific's August 16, 2002 Comments in Nos. 01P-0572 and 02P-0075, at 4-10; Star Scientific's Response to the October 1, 2002 Comments of GlaxoSmithKline Consumer Healthcare, LP, at 3-4.

[5] See Star Scientific's May 1, 2002 Comments in No. 02P-0075, at 15-17; Star Scientific's May 1, 2002 Comments in No. 01P-0572, at 12-14, Star Scientific's August 16, 2002 Comments in Nos. 01P-0572 and 02P-0075, at 7-8; Star Scientific's Response to Petitioner's October 1, 2002 Comments, at 4.

4408(1). Thus, regardless of how many times Star Scientific publicly describes Ariva as an innovative tobacco product, the Petitions to regulate Ariva must be denied because Ariva is a tobacco product over which "Congress has clearly precluded the FDA from asserting jurisdiction." *Brown & Williamson*, 529 U.S. at 126.

3. Finally, Petitioner alleges that Star Scientific made an "implied smoking cessation claim" for Ariva by citing a survey indicating that many people who use Ariva have decreased their daily cigarette intake, and some have transitioned completely from cigarettes to Ariva. Petitioner's November 26, 2002 Comments at 2. Petitioner is wrong. As we previously explained, Star Scientific has not marketed Ariva as a smoking cessation product. Instead, Ariva is marketed as a *tobacco product* that can be used by smokers in situations where they cannot smoke and by smokeless tobacco users who want a smokeless tobacco product that does not require expectoration.[6] Petitioner's newly submitted evidence thus simply confirms that people use Ariva as it is marketed: as a tobacco product that provides an alternative to other tobacco products.

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[6] See, *e.g.*, Star Scientific's May 1, 2002 Comments in No. 01P-0572, at 4, 14-15.

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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