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MCDERMOTT, WILL & EMERY

July 31, 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 State Attorneys General 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 by the State Attorneys General on the Citizen Petitions referenced above filed concerning Star Scientific's compressed powdered hard tobacco product, Ariva™ Cigalett™ picces.

The State Attorneys General comments do not contribute any new information concerning the legal question of whether the Food and Drug Administration ("FDA") has the authority to regulate Ariva™ as a "drug" or "food" under the Federal Food, Drug and Cosmetic Act ("FDCA.") Because the additional comments of the State Attorneys General state no basis upon which jurisdiction can be assumed by FDA, the comments should not be accorded any weight in considering the above referenced Citizen Petitions.

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,



David L. Rosen

02P-0075

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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™

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Docket Nos.: 01P-0572 &
02P-0075

STAR SCIENTIFIC, INC.'S RESPONSE TO THE COMMENTS
OF THE STATE ATTORNEYS GENERAL

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The Attorneys General contribute nothing new to the resolution of the legal question whether the Food and Drug Administration (FDA) has the authority to regulate Ariva™ as a “drug” or “food” under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* The tip-off that the Attorney Generals have nothing to say on this subject is that they do not discuss either the FDCA “food” and “drug” definitions or the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA), 15 U.S.C. §§ 4401-4408. Indeed, they cannot anywhere bring themselves to use the words “smokeless tobacco.” Instead, they use a term – “traditional tobacco product” – that has no agreed meaning or definition in the statutes or case law, and then seek to demonstrate that Ariva falls outside of that term.¹ This is not legal analysis. It is pure spin.

The Attorneys General, like the Petitioners, do not (and cannot) come to grips with the fact that Ariva™ is simply a compressed form of Star Scientific’s Stonewall™ dry snuff that is manufactured under a license from

¹ As we explained in our prior comments, the term “traditional tobacco products” is not found in either *FDA v. Brown & Williamson*, 529 U.S. 120 (2000), or the CSTHEA on which the Court relied. Instead, the Court held that “Congress’ tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed” (529 U.S. at 156), which, in the context of that litigation, meant tobacco products marketed “without manufacturer claims of therapeutic benefit.” (*Id.* at 127). See Star Scientific’s May 1, 2002 Comments in Docket No. 02P-0075, at 17-18; Star Scientific’s May 1, 2002 Comments in Docket No. 01P-0572, at 12-13.

the Bureau of Alcohol, Tobacco and Firearms (BATF), is taxed as a “snuff” under federal excise laws, 26 U.S.C. § 5701, *et seq.*, and is subject to the warning requirements of the CSTHEA and implementing Federal Trade Commission (FTC) regulations. Thus, nothing in the Attorneys General’s comments undermines the validity of Star Scientific’s argument (made in its Comments filed on May 1, 2002) that Ariva is a “smokeless tobacco” product subject to the CSTHEA, not a “food” or “drug” subject to FDA regulation under the FDCA. Instead, the Attorneys General make a number of assertions about Ariva that are either incorrect or irrelevant.

1. The Attorneys General cite the supposed chemical analysis of Ariva offered by Petitioner GlaxoSmithKline to argue that Ariva contains numerous harmful substances. (AG Comments at 3-4). Even assuming, for sake of argument, the accuracy of this chemical analysis, it is irrelevant.² Even if Ariva contains some dangerous ingredients,³ that is not a basis for

² As we have pointed out, Petitioner’s chemical analysis neither indicates which of the potentially harmful substances are present in other tobacco products, such as cigarettes and moist or dry snuff, nor indicates whether there are potentially harmful substances in other tobacco products that are not present in Ariva. See May 1 Comments in Docket No. 02P-0075, at 14, n.14; May 1 Comments in Docket No. 01P-0572, at 11, n.16.

³ The Attorneys General see fit to mention four “potentially toxic and carcinogenic compounds” purportedly found in Ariva. Three of these are found in all tobacco products, and two are widely found in a variety of other

FDA regulation because, as we have explained in our prior Comments, Ariva is a “smokeless tobacco” product within the meaning of the CSTHEA, and not a “food” or “drug” under the FDCA.⁴

Indeed, although the Attorneys General assert (without any support) that Ariva is “[l]ike a candy lozenge,” (AG Comments at 4), their complaints about the possible health implications of the use of Ariva demonstrate that they are concerned because Ariva is being used as a tobacco product, and not as a food. The Attorneys General express concern that use of Ariva could impair efforts to reduce consumption of *tobacco products* by “undermin[ing] both the de-normalization of tobacco product use achieved by smoke-free areas” and the “support smoke-free laws provide for smokers seeing to reduce their tobacco consumption and quit.” (AG Comments at 8).

Because Ariva is a tobacco product, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 156 (2000), precludes FDA from asserting jurisdiction to regulate Ariva unless Star Scientific makes claims of

common products. The fourth, the xylenes, are distributed throughout the environment; they have been detected in air, rainwater, soils, surface water, drinking water and aquatic organisms. Curiously, the Attorneys General do not mention the tobacco specific nitrosamines (TSNAs), widely recognized potent carcinogens which, while present in cigarette smoke and virtually all other smokeless tobacco products, are almost undetectable in Ariva.

⁴ See May 1 Comments in Docket No. 01P-0572, at 10-12; May 1 Comments in Docket No. 02P-0075, at 13-15.

therapeutic benefit for the product. As we previously demonstrated, Star Scientific does not make claims of therapeutic benefit for Ariva.⁵ Instead, the Ariva package states that (1) Ariva is “A Smokeless Tobacco Product” composed of “Compressed Powdered Tobacco”, and (2) “There are No safe tobacco products. Quitting or Not starting is your best option.”⁶ The package also contains the health warnings mandated by the CSTHEA. In light of these express statements and warnings, the Attorneys General’s assertion (at 7) that the picture of the blue sky and water on the package, and the statement that Ariva is for adult use only, somehow constitute an implied health claim that Ariva is safe for adults is absurd.⁷

2. The Attorneys General’s assertion that *Brown & Williamson* has no application to Ariva is equally erroneous. Quoting language from *Brown & Williamson* explaining that if Congress has not specifically addressed an

⁵ See May 1 Comments in Docket No. 01P-0572, at 15-18.

⁶ Exhibit 4 to May 1 Comments in Docket No. 02P-0075; Exhibit 5 to May 1 Comments in Docket No. 01P-00572.

⁷ The Attorneys General also allege (at 7 & n.17) that the Ariva package, which states that it contains “20 Cigalett™ pieces (Compressed Powdered Tobacco)”, is misleading because it “implies [that tobacco] is the only ingredient in Ariva.” The Attorneys General are mistaken. The statement that Ariva contains tobacco implies only what the package expressly states: that Ariva is “A Smokeless Tobacco Product.” See Exhibit 4 to May 1 Comments in Docket No. 02P-0075; Exhibit 5 to May 1 Comments in Docket No. 01P-00572.

issue, courts defer to the agency's construction of the statute because of the agency's "greater familiarity" with the "changing facts and circumstances surrounding the subjects regulated," (529 U.S. at 132), the Attorneys General maintain that FDA may regulate Ariva because Ariva is not a "traditional tobacco product," and FDA has "great familiarity" with the regulation of "foods" and "drugs." (AG Comments at 5). The problem with this analysis is that it ignores the subsequent paragraph of the *Brown & Williamson* decision in which the Court held that such deference to FDA's decision to regulate tobacco products as "drugs" under the FDCA was inappropriate because "Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products."⁸ *Brown & Williamson*, 529 U.S. at 133.

3. The Attorneys General also make some serious observations regarding the appropriate public policy response to tobacco products that pose health hazards or are attractive to young people. It is noteworthy that the Attorneys General do not question our contentions that Star Scientific (1)

⁸ Our previous Comments demonstrated that the holding of *Brown & Williamson* is not limited to so-called "traditional tobacco products," but rather deprives FDA of jurisdiction to regulate all tobacco products, including products like Ariva that are "smokeless tobacco" products subject to the CSTHEA. See May 1 Comments in Docket No. 01P-0572, at 12-14; May 1 Comments in Docket No. 02P-0075 at 15-17.

does not target youth in its marketing, and (2) requires retailers to observe the same cautions to prevent purchases by underage consumers that are in place for other tobacco products.⁹ Beyond that, the Attorneys General's observations are made to the wrong body. Star Scientific has long and consistently maintained that Congress *should* give FDA the authority to regulate the manufacture, sale, distribution, labeling and marketing of *all* tobacco products.¹⁰ But as the Supreme Court held in the *Brown & Williamson* decision that the Attorneys General cannot bring themselves to accept, Congress has made a different choice. "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." *Brown & Williamson*, 529 U.S. at 159-160. Thus, unless and until Congress enacts new legislation giving FDA this

⁹ Although the Attorneys General do allege (at p.5) that Ariva might be appealing "to youthful new users," they provide no evidence that Ariva actually is available to minors, is attractive to that group, or will be used as a "gateway" to tobacco use. Indeed, the record evidence shows that Ariva is kept behind the counter in stores, with the tobacco products, and is not displayed in the candy aisle, where it would be easily accessible to minors.

¹⁰ See, e.g., May 1 Comments in Docket No. 01O-0572, at 2, 24 & Attachment 1.

authority, the agency may not regulate Ariva or any other tobacco product,
absent claims of therapeutic benefit that are not present here.

Respectfully Submitted,

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