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MCDERMOTT, WILL & EMERY

May 1, 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 Comments
Concerning Citizen Petition Docket No. 02P-0075

Dear Sir/Madam:

We are writing on behalf of our client Star Scientific, Inc. In following up on my letter of March 5, 2002, I am enclosing a formal response to the above referenced Citizen Petition concerning Star Scientific's compressed powdered hard tobacco product, Ariva™ Cigalett™ pieces.

We firmly believe 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). The Ariva™ compressed powdered tobacco product is neither a food nor a food additive as defined under the Federal, Food, Drug and Cosmetic Act. The Petition is without merit and should be denied.

Sincerely yours,



David L. Rosen

02P-0075

C3

cc: Charles Fried, Esq.

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

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General Counsel
Star Scientific, Inc.

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INTRODUCTION

Star Scientific, Inc. submits this response to oppose a Citizen Petition filed on February 15, 2002 by GlaxoSmithKline Consumer Healthcare, LP asking the Food and Drug Administration (FDA) to regulate Ariva™ (Ariva) compressed smokeless tobacco "cigalett"™ (cigalett) pieces as "foods" within the meaning of the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.* As we explain in detail below, the Petition should be denied, because it is based on the factually erroneous assertion that Ariva is a "flavored candy-like product containing tobacco." (Petition at 1). On the contrary, Ariva is a compressed, powdered tobacco product used by adult tobacco users for tobacco satisfaction. Ariva is, therefore, not a "food" within the meaning of the FDCA. It is a smokeless tobacco product that the Bureau of Alcohol, Tobacco and Firearms (BATF) has classified as a "snuff" subject to the federal excise tax and licensing requirements applicable to the manufacture and sale of smokeless tobacco products, 26 U.S.C. § 5701, *et seq.* As a smokeless tobacco product, Ariva is also subject to the warning requirements of the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. §§ 4401-4408, and implementing Federal Trade Commission (FTC) regulations. Thus, under the Supreme

Court's decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), Ariva is outside the scope of FDA's jurisdiction.

STATEMENT OF FACTS

Star Scientific is a technology-oriented tobacco company with a mission centered upon the reduction of toxins in tobacco leaf and tobacco smoke. Star Scientific has developed and implemented a patented and commercially feasible non-chemical (StarCured™) tobacco curing technology that significantly reduces the formation of tobacco-specific nitrosamines (TSNAs), which respected scientists believe are cancer-causing toxins in tobacco leaf. In addition to sublicensing this tobacco curing technology to other companies, Star Scientific is engaged in the development of tobacco products using StarCured™ tobacco. One of these tobacco products is Ariva, which Star Scientific began selling on November 14, 2001 in test-markets in Dallas, Texas and Richmond, Virginia.¹

The ingredients in Ariva are identical to those in Stonewall™ dry snuff, another of Star Scientific's smokeless tobacco products. Both Ariva and Stonewall dry snuff are made of powdered Virginia StarCured™ tobacco and contain mint, eucalyptus and other natural and artificial

¹ See Press Release, Star Scientific, Inc., "Star Scientific Announces Test Market of Ariva Smokeless Tobacco Cigarettes" (Attachment 1).

flavorings and ingredients that are commonly found in smokeless tobacco products and cigarettes. The only difference between the two smokeless tobacco products is that Ariva is compressed into cigarette pieces.

Because nicotine is a naturally occurring alkaloid in tobacco, and the primary ingredient in Ariva is powdered tobacco, Ariva contains the same natural nicotine as do all other smokeless and smoked tobacco products. The level of nicotine in an Ariva cigarette is comparable to that in a light cigarette.²

Ariva is a smokeless tobacco product for adult smokers who find themselves in situations and environments where they cannot, or do not want to, smoke and for smokeless tobacco users who want a smokeless tobacco product that does not require expectoration.³ A package of 20 Ariva cigarettes sells for a retail price of around four dollars, which is comparable to the cost of premium cigarettes and snuff.

Because Ariva is a smokeless tobacco product, its packaging contains the health warnings required by the Comprehensive Smokeless Tobacco

² See Star Scientific, "QUESTIONS AND ANSWERS", a Fact Sheet for Distribution to Public Health Colleagues, at 2 (Attachment 2).

³ See Press Release, Star Scientific, "Star Scientific And B&W Enter Into Contracts for Purpose Of StarCured Tobacco, Development and Sale of Very-Low TSNA Smoked and Smokeless Tobacco Products," at 1 (Attachment A to the Petition).

Health Education Act of 1986, 15 U.S.C. § 4402, and the implementing FTC regulations, 16 C.F.R. § 307.2. As required by those regulations, each package of Ariva contains one of the following warnings:

(1) WARNING: THIS PRODUCT MAY CAUSE MOUTH
CANCER;

(2) WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE
AND TOOTH LOSS;

(3) WARNING: THIS PRODUCT IS NOT A SAFE
ALTERNATIVE TO CIGARETTES.

16 C.F.R. § 307.4(a); see also 15 U.S.C. § 4402(a)(1).

The Bureau of Alcohol, Tobacco and Firearms (BATF) has also determined that Ariva is a "smokeless tobacco product" within the meaning of the Internal Revenue Code, which imposes federal excise taxes on tobacco products and requires businesses engaged in the manufacture of tobacco products to obtain a license from BATF.⁴ 26 U.S.C. § 5701, *et seq.* BATF granted Star Scientific a license to manufacturer Ariva, and Ariva is

⁴ The Internal Revenue Code defines "smokeless tobacco" as "any snuff or chewing tobacco" and defines "snuff" as "any finely cut, ground, or powdered tobacco that is not intended to be smoked." 26 U.S.C. §§ 5702(m)(1), 5702(m)(2); see also 27 C.F.R. § 275.11 (same definition in BATF regulations).

taxed as a "snuff" tobacco product. This is the same tax designation that is applied to Stonewall dry snuff.

Ariva is sold under the same rules, regulations and requirements that govern all tobacco products.⁵ Thus, Ariva is kept in the same location in stores as other tobacco products, and purchase requires valid proof of age.⁶ In addition, each package of Ariva includes the following prominent labeling: "Underage Sale Prohibited", and "THIS PRODUCT IS FOR ADULT TOBACCO USERS ONLY".⁷

Ariva is also the first tobacco product to use child-resistant packaging: The cigarett pieces are sold in blister packs of 20. Star Scientific chose this packaging after reviewing poison control data on the annual incidence of toxicity arising from toddlers' accidental ingestion of tobacco products.⁸

⁵ See QUESTIONS AND ANSWERS, *supra* note 2, at 3.

⁶ See, Star Scientific, "WHAT IS ARIVA™?", a Fact Sheet for Distribution to Public Health Colleagues (Attachment 3).

⁷ Ariva Label (Attachment 4).

⁸ ARIVA™ FACT SHEET (Attachment 5).

REASONS FOR DENYING THE PETITION

Ariva Cigaretts Are Not "Foods" Within The Meaning Of The FDCA.

Petitioner contends that Ariva cigarette should be considered an adulterated "food" containing a "food additive" (tobacco) that is not generally recognized as safe for use in foods. (Petition at 1, 4-6). That contention should be rejected for two independent reasons. First, Ariva is not a "food" within the meaning of the FDCA (and, therefore, the tobacco in Ariva is not a "food additive" either). Second, the reasoning the Supreme Court used in holding that tobacco products are outside the scope of the "drug" provisions of the FDCA is equally applicable to the "food" provisions of the statute. Thus FDA lacks jurisdiction to regulate Ariva as a food.

1. Ariva is not a "food" within the meaning of the FDCA. That statute defines "food" as "articles used for food or drink for man or other animals;" a "chewing gum," or "articles used for components of any such article." 21 U.S.C. § 321(f). Petitioner does not claim that Ariva is a chewing gum or a component of some food product. Instead, Petitioner claims that Ariva is an "article[] used for food," 21 U.S.C. § 321(f)(1), that is, an article "used by people in the ordinary way most people use food -- primarily for taste, aroma or nutritive value." *Nutrilab, Inc. v. Schweiker*,

713 F.2d 335, 337 (7th Cir. 1983).⁹ But Petitioner has no support for this claim other than its bald assertion that Ariva must be used for food, because, in its view, Ariva is a "flavored candy-like product[] containing tobacco." (Petition at 5). Petitioner is wrong.

Certainly people use Ariva because they like it: they like the tobacco satisfaction it provides. But if that makes Ariva a "food," then so are cigarettes, snuff and chewing tobacco foods, which plainly they are not. This argument is an example of Petitioner's unwillingness to accept the teaching of *Brown & Williamson* that Congress has devised a distinct regulatory scheme for tobacco products, and that the FDCA regime is not to be twisted into applications Congress did not intend. See *infra* at 10-12.

Moreover, Ariva is not a "candy-like product" that must be used for food, as Petitioner suggests. Ariva is a compressed version of Stonewall dry snuff, a smokeless tobacco product that no one has ever suggested is "candy-like" or "used for food." The only difference between Stonewall dry snuff and Ariva is that Ariva is compressed into a hard pellet, while Stonewall dry

⁹ Petitioner errs in citing *Nutrilab* for the proposition that Ariva could be a food even if it is "*not* used primarily for taste, aroma or nutritive value." (Petition at 5 (emphasis added)). Instead, *Nutrilab* held that an article is "used for food" if it *is* "used by people in the ordinary way most people use food -- primarily for taste, aroma or nutritive value," even if it is not used solely for those purposes. 713 F.2d at 337.

snuff remains in powdered form. The ingredients in the two smokeless tobacco products are exactly the same, and there is no "candy" coating added to the Ariva cigarett. See *supra* at 2-3. Consequently, Ariva does not taste like candy. Instead, it has a tobacco taste described by some as slightly bitter.¹⁰

Nor is Ariva marketed as a candy. The Ariva package does not claim that the product is a candy, or even mention that it has a mint flavor. Instead, Ariva is marketed as a tobacco product to be used by smokers in situations where they cannot, or do not want to, smoke. The Ariva package states that it contains "20 Cigarette™ pieces (Compressed Powdered Tobacco)", and that Ariva is "A Smokeless Tobacco Product" for use "when you might have a cigarette but can't."¹¹ And because it is a tobacco product, it is sold not in the candy aisle of stores, but with other tobacco products pursuant to the rules, regulations and taxes that are applicable to the sale of tobacco products. See *supra* at 5.

These facts distinguish Ariva from the "Masterpiece Tobacs" product cited in the Petition (at 5). FDA rejected the manufacturer's claim that "Masterpiece Tobacs" was a smokeless tobacco product, and instead

¹⁰ QUESTIONS AND ANSWERS, *supra* note 2, at 3.

¹¹ Ariva Label, *supra* note 7.

determined that "Masterpiece Tobacs" was a "food" because it looked, tasted, and chewed like a chewing gum, and it contained a chewing gum base as well as tobacco.¹² In making this determination, FDA relied on *United States v. Technical Egg Products, Inc.*, 171 F. Supp. 326, 328 (N.D. Ga. 1959), which held that items that are generally regarded as foods are "foods" within the meaning of the FDCA, even if the seller claims that he does not intend to sell the items for human consumption. Thus, the court held that rotten eggs, which the distributor claimed would not be sold for human consumption, were nonetheless "foods" within the meaning of the FDCA because eggs are generally regarded as foods and "a rotten egg is one differing only in degree rather than in kind from a sound egg." *Id.*; see also *United States v. 52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940) (maple syrup containing unduly high concentrations of lead is a "food" even though the distributor claimed that he would remove the lead before selling it to consumers because maple syrup is generally regarded as a food).

As noted above, "chewing gum" is specifically classified as a "food" under the FDCA, 21 U.S.C. § 321(f)(2). But Ariva is not a chewing gum.

¹² Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA, to Stuart Pape, April 12, 1988, at 1 (Attachment G to the Petition).

Nor is Ariva the kind of product that is generally regarded as a food.

Instead, it is a smokeless tobacco product that contains the same ingredients found in other smokeless tobacco products, is used for tobacco satisfaction, as are other smokeless tobacco products, and is marketed and regulated as a tobacco product. There is, therefore, no basis for concluding that Ariva is a "food" under the FDCA.¹³

2. Although *Brown & Williamson* did not specifically address the question whether FDA has authority to regulate tobacco products as "foods" under the FDCA, the analysis the Supreme Court used in holding that tobacco products are not "drugs" compels the conclusion that they are not "foods" either. The Court rejected FDA's attempt to regulate tobacco products as "drugs" because it concluded that:

¹³ Nothing in the letter from an official of the Foods Standards Agency of the United Kingdom (attached to the Petition as Exhibit A) supports Petitioner's contention that Ariva is a food. That letter was prompted by an article written in the Sunday Times on May 6, 2001, before Ariva was even test-marketed, that erroneously characterized Ariva as a "nicotine sweet." Based on that erroneous newspaper article, an official of the Food Standards Agency of the United Kingdom advised Star Scientific that Ariva might be classified as a food under European Union regulations. See Exhibit A to the Petition. Star Scientific promptly responded with a letter describing the inaccuracies in the newspaper article, and explaining that Ariva is a smokeless tobacco product, not a food. See Exhibit B to the Petition. After receipt of this letter from Star Scientific, neither the Food Standards Agency of the United Kingdom, nor any agency in any other EU country, has taken any action to regulate Ariva as a food.

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.

The Court reasoned that "[v]iewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use." *Brown & Williamson*, 529 U.S. at 133 (quoting 21 U.S.C. § 393(b)(2)). But in the rulemaking to regulate tobacco products, FDA documented that tobacco products are "unsafe" and "dangerous." *Brown & Williamson*, 529 U.S. at 134 (quoting 61 Fed. Reg. 44412 (1996)). This would "logically imply" that if tobacco products were subject to the FDCA, the "FDA would be required to remove them from the market." *Brown & Williamson*, 529 U.S. at 135. Congress, however, "has foreclosed the removal of tobacco products from the market" and instead "has directly addressed the problem of tobacco and health" through tobacco-specific labeling laws, such as the Federal Cigarette Labeling and Advertising Act (FCLAA), and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA). *Id.* at 137.

Brown & Williamson thus compels the conclusion that FDA lacks

jurisdiction to regulate Ariva. Ariva is a smokeless tobacco product within the meaning of the CSTHEA, one of the tobacco-specific statutes on which the Court relied. See *infra* at 13-15. Moreover, what Petitioner is asking FDA to do -- to ban the sale of Ariva unless Star Scientific can prove that it is safe for human consumption -- runs counter to the CSTHEA and other tobacco-specific statutes whose "collective premise" is that "cigarettes and smokeless tobacco will continue to be sold in the United States." *Brown & Williamson*, 529 U.S. at 139. Instead of subjecting tobacco products to FDA regulation under the FDCA, Congress "has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising," and has "persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health." *Id.* at 156. Thus, FDA should not be able to use the "food" provisions of the FDCA to regulate the sale of smokeless tobacco products any more than it should be able to accomplish that objective by using the "drug" provisions of the statute. Tobacco products are simply outside the scope of the FDCA.

None of Petitioner's attempts to avoid this conclusion are persuasive.

a. Petitioner states that *Brown & Williamson* does not deprive FDA of jurisdiction over Ariva because, in Petitioner's view, Ariva is a "candy-

like" product that falls outside the scope of the CSTHEA and the related smokeless tobacco provisions of the Internal Revenue Code. (Petition at 10). Petitioner is wrong. The CSTHEA defines "smokeless tobacco" as "any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1). Ariva falls squarely within that definition. As explained above, Ariva is composed of powdered tobacco that is compressed into a cigarette intended to be placed in the oral cavity. Ariva also contains the flavorings that are contained in Stonewall dry snuff and are commonly found in other smokeless tobacco products as well. Indeed, Ariva is nothing more than a compressed version of Stonewall dry snuff. See *supra* at 2-3.

Petitioner nonetheless asserts that Ariva is not a smokeless tobacco product because consumers of Ariva will not have to expectorate. (Petition at 5, 10). This, too, is incorrect. The CSTHEA does not make expectoration a defining attribute of a "smokeless tobacco" product; indeed, expectoration is not mentioned in the statutory definition at all. Smokeless tobacco products come in many forms, including powdered snuff, whole or ground loose leaf tobacco, individual pouches, and hardened blocks or ropes of tobacco. These products are frequently advertised as containing flavorings such as menthol, eucalyptus, spearmint, citrus, vanilla, wintergreen, cherry,

lemon, and even Irish Whiskey.¹⁴ Some of these products are intended to dissolve in the oral cavity and do not require expectoration. For example, dry snuff can be rubbed on the gums and allowed to dissolve in the mouth like Ariva does.¹⁵ There are also chewing tobacco bits that are intended to dissolve in the mouth and contain labels stating that expectoration is not

¹⁴ On April 26, 2002, as we were preparing to file this response to the Petition, Petitioner submitted a letter including what it claims is an analysis of the chemical constituents of Ariva. Petitioner argues that this analysis demonstrates that Ariva is not simply a "compressed hard tobacco product" because Ariva contains, among other things, "sweeteners" and "flavoring ingredients." Glaxo Letter at 2. We have not had time to review the letter in detail, and we reserve the right to make additional submissions in response to the letter at a later date. But even assuming, for the sake of argument, the accuracy of Petitioner's chemical analysis, it does not establish that Ariva is a "food" or "drug" within the meaning of the FDCA, as Petitioner claims (at 2 & n.5). As we discuss in the text above, tobacco products typically contain sweeteners and natural and artificial flavorings and ingredients. See Snuff Types, available at <<<http://www.snuffshop.com>>>; and Snuff Products, available at <<<http://www.cigarettesamerica.com>>>. Indeed, it is notable that Petitioner did not compare Ariva's alleged constituent elements with those of other undoubted tobacco products, such as cigarettes and moist and dry snuffs.

The Glaxo Comment also erroneously states that Star Scientific has made Ariva available for sale over the Internet. See Glaxo Comment at 2. Star Scientific does not sell Ariva over the Internet, and it monitors the Internet in an attempt to prevent tobacco distributors from engaging in such sales. After Star Scientific contacted the Internet tobacco distributor identified in the Glaxo Comment, the distributor removed Ariva from its list of available tobacco products and now notes: "Sorry! This tobacco product is no longer available at this time."

¹⁵ As far as we have been able to determine, there are approximately 10 manufacturers and approximately 75-80 different brands of dry snuff alone.

required.¹⁶ The CSTHEA's definition of "smokeless tobacco" encompasses all of these forms, because it includes "*any* finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1) (emphasis added).

Moreover, BATF has determined that Ariva is a "smokeless tobacco product" within the meaning of the similar definition in the Internal Revenue Code.¹⁷ BATF granted Star Scientific a license to manufacture Ariva, and Ariva is taxed as a "snuff" tobacco product. See *supra* at 4.

b. Petitioner also erroneously asserts that *Brown & Williamson* only precludes FDA from asserting jurisdiction over "traditional tobacco products" and does not extend to "candy-like" products like Ariva. (Petition at 7-8). As just explained, Ariva is not a "candy-like" product. It is a smokeless tobacco product governed by the CSTHEA.

¹⁶ For example, the label from Oliver Twist Chewing Tobacco Bits describes the product as a "Smokeless tobacco" that the user should "keep between gum and cheek -- don't chew -- it's long lasting and slowly melts giving you secret tobacco satisfaction without expectorating." (Attachment 6).

¹⁷ The Internal Revenue Code defines "smokeless tobacco" as "any snuff or chewing tobacco" and defines "snuff" as "any finely cut, ground, or powdered tobacco that is not intended to be smoked." 26 U.S.C. §§ 5702(m)(1), 5702(m)(2); see also 27 C.F.R. § 275.11 (same definition in BATF regulations).

Moreover, *Brown & Williamson* did not hold that FDA lacks jurisdiction only to regulate what Petitioner deems to be a "traditional" tobacco product. That term is not found in either the *Brown & Williamson* decision or the tobacco-specific statutes on which the Court relied. Instead, *Brown & Williamson* held that "there is no room for *tobacco products* within the FDCA's regulatory scheme" (529 U.S. at 143 (emphasis added)) and that "Congress' tobacco-specific statutes preclude the FDA from regulating *tobacco products as customarily marketed*" (*id.* at 156 (emphasis added)). As even Petitioner concedes (at 7), the Supreme Court used the term "tobacco products as customarily marketed" in the same way that FDA used the term in the challenged rulemaking and subsequent litigation -- that is, to refer to tobacco products marketed "without manufacturer claims of therapeutic benefit." *Brown & Williamson*, 529 U.S. at 127; see also *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 161 n.9 (4th Cir. 1998) (noting that FDA's brief used the term "customarily marketed" 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."), *aff'd*, 529 U.S. 120 (2000); Petition for Writ of Certiorari, *FDA v. Brown & Williamson Tobacco Corp.*, No. 98-1152 at 12, n.3 (noting FDA's agreement with the Fourth Circuit's use of the term "customarily

marketed"). Star Scientific does not make any claims of therapeutic benefit for Ariva. Thus, Ariva is a "tobacco product" that falls outside the FDCA's regulatory scheme as interpreted in *Brown & Williamson*.

c. Finally, Petitioner states that *Brown & Williamson* would permit FDA to regulate Ariva so long as FDA ensures that there is no "direct conflict" between the FDCA and the tobacco-specific laws. In Petitioner's view, this could be accomplished if FDA were to waive certain provisions of the FDCA to permit the Ariva label to include the warnings required by the CSTHEA and to avoid disclosure of Ariva's ingredients that are protected by the confidentiality provisions of the CSTHEA. (Petition at 8-9). This argument fails, because it underestimates the scope of the conflict between the FDCA and the nation's tobacco laws, and misconstrues the *Brown & Williamson* opinion.

Petitioner's statement that it is "only" asking FDA to require Star Scientific "to submit a food additive petition prior to marketing [Ariva]" (Petition at 8) masks the reality of the situation. If the Petition were granted, Star Scientific could not sell Ariva unless it obtains FDA's permission to use tobacco in Ariva. To obtain such permission, Star Scientific would have to file a lengthy food additive petition for tobacco, containing, among other things:

(B) a statement of the conditions of the proposed use of [tobacco], including all directions, recommendations, and suggestions proposed for the use of [tobacco], and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect [tobacco] is intended to produce, and the quantity of [tobacco] required to produce such effect;

* * *

(E) full reports of investigations made with respect to the safety for use of [tobacco], including full information as to the methods and controls used in conducting such investigations.

21 U.S.C. § 348(b)(2). And even after such a petition were filed, Star Scientific still could not sell Ariva unless FDA determines that tobacco can be safely used as a food additive in Ariva. 21 U.S.C. § 348 (c). This result would be inconsistent with laws that "foreclose[] the removal of tobacco products from the market." *Brown & Williamson*, 529 U.S. at 137.

Moreover, the approach that Petitioner advocates -- that FDA stretch the "food" provisions of the FDCA to cover tobacco products, and then make exceptions to those provisions that are incompatible with tobacco-specific laws such as the CSTHEA -- is the same approach that the Supreme Court rejected with respect to the FDCA's "drug" provisions. After extensively reviewing the history of the nation's tobacco laws, the Court concluded:

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.

Brown & Williamson, 529 U.S. at 159-160. That reasoning is equally applicable to the "food" provisions of the FDCA. Tobacco products are simply not covered by that statute.

* * * * *

As we have already explained, Star Scientific acknowledges that all tobacco products -- including Ariva -- pose risks to human health. For this reason, Star Scientific supports efforts to give FDA jurisdiction to implement fair and meaningful regulations over the manufacture, sale, distribution, labeling and marketing of *all* tobacco products. But as the Supreme Court explained in *Brown & Williamson*, Congress has made a different choice. Instead of subjecting smokeless tobacco products to FDA regulation under the FDCA, Congress enacted the CSTHEA, which requires, among other things, that smokeless tobacco products contain specified health warnings (15 U.S.C. § 4402(a)(1)), and that manufacturers provide the Secretary of Health and Human Services with a list of the ingredients

and the amount of nicotine contained in their smokeless tobacco products (*id.* § 4403(a)). The Secretary may then conduct research and report to Congress information about any ingredient he believes to pose "a health risk to users of smokeless tobacco", or any other information he "determines to be in the public interest." *Id.* § 4403(b)(1).

Although the CSTHEA is not Petitioner's preferred way to protect the public from the dangers of smokeless tobacco products, that is the system chosen by Congress, and it must be applied equally to Ariva and all other smokeless tobacco products. As explained above, Petitioner's attempt to limit the CSTHEA to what it believes to be "traditional" tobacco products, while extending the FDCA to tobacco products like Ariva finds no support in the text of the CSTHEA or the *Brown & Williamson* decision. What the Supreme Court said in *Brown & Williamson* is equally true in this case: "in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop. Reading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given the FDA the authority" to regulate tobacco products absent claims of therapeutic benefit by the manufacturer. 529 U.S. at 161 (internal quotations and citations omitted).

CONCLUSION

For these reasons, the Petition for Regulation of Ariva should be denied.

Dated May 1, 2002

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