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October 1, 2002

BY HAND

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

**Re: Citizen Petitions Requesting FDA to Regulate Candy-like Products
Containing Tobacco as Adulterated Food Products (Docket Nos. 01P-
0572 and 02P-0075)**

Dear Sir or Madam:

On behalf of GlaxoSmithKline Consumer Healthcare ("GSK"), we are writing to respond to the letters submitted by Star Scientific, Inc. ("Star") in the above-referenced dockets on July 22, 2002, and August 16, 2002. As explained in detail below, the Food and Drug Administration ("FDA") must reject Star's flawed reading of the law set forth in the latter letter. Nothing in FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) ("Brown & Williamson"), or the body of case law and administrative findings surrounding the definition of "food" under the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 321, exempts Ariva™ from regulation by FDA. At the same time, FDA should not be misled by the implication in Star's blustery letter of July 2002 that it need not worry about sales of Ariva to minors over the Internet. In fact, at least one website operated by an independent tobacco distributor continues to advertise, sell, and even give the product away without exercising necessary protections.

In connection with responding to Star's most recent comments, GSK has reviewed the relevant statutory provisions, case law, and administrative record currently before FDA. That analysis demonstrates that:

(A) Ariva satisfies the court's test in Nutrilab, Inc. v. Schweiker, 713 F.2d 335 (7th Cir. 1983) ("Nutrilab"), for a food product and, even if it does not, that court's

02P-0075

RC 4

Dockets Management Branch, FDA

October 1, 2002

Page 2 of 23

narrow interpretation of the term “food” in section 321(g) of the Act does not control the questions currently before FDA (pages 2 to 6);

(B) As FDA concluded in the Masterpiece Tobacs case, the FDCA’s definition of food in Section 321(f) is expansive and it includes products containing tobacco such as Ariva when they are sold in food form (pages 6 to 10);

(C) Nothing in the Brown & Williamson decision undermines FDA’s sweeping authority to regulate Ariva as an adulterated food product under the FDCA (pages 10 to 17);

(D) The FDA need not determine that Ariva is not a “smokeless tobacco product” under the Comprehensive Smokeless Tobacco Health Education Act, 15 U.S.C. §§ 4401-4408 (“CSTHEA”), to grant GSK’s petition (pages 17 to 21); and

(E) Inasmuch as Internet sales are not sufficiently controlled to ensure that minors do not have access to tobacco products, candy-like products containing tobacco such as Ariva raise especially significant concerns (pages 21 to 23).

In light of these conclusions and in the face of new information from Star indicating that Ariva is now available in at least 30,000 stores,¹ FDA must take the regulatory actions requested by GSK in its citizen petition.

A. Ariva Satisfies the Nutrilab Court’s Test for a Food Product and, Even if it Does Not, That Court’s Narrow Interpretation of the Term “Food” In Section 321(g) of the Act Does Not Control the Questions Currently Before FDA.

At the outset, Star contends that Ariva does not fall within the broad definition of “food” contained in the FDCA. 21 U.S.C. § 321(f). To that end, Star relies heavily on the decision of the U.S. Court of Appeals for the Seventh Circuit in Nutrilab, Inc. v. Schweiker. There, the court declared 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 338. Star claims that Ariva is outside

¹ In a press release dated August 15, 2002, Star reported that: “At the end of the second quarter, Ariva was available in more than 30,000 retail locations, exceeding our first-quarter projections for retail placement volume. This includes the majority of CVS stores, over 2000 Albertson’s stores, and approximately 600 7-Eleven franchise convenience stores. We anticipate that Ariva(TM) also will be available in the 3400 Rite Aid stores by September 1.” See Press Release, Star Scientific, Inc., Star Scientific, Inc. Reports Second Quarter Results, Continues National Rollout of Ariva (Aug. 15, 2002) (attached as Exhibit A).

Dockets Management Branch, FDA
October 1, 2002
Page 3 of 23

the scope of the FDCA's definition of food because people do not use Ariva for these purposes. Rather, Star declares, people only use Ariva because "they like the tobacco satisfaction it provides" and that is different from using the product for its taste, aroma or nutritive value.² As explained below, Star's position is utterly inconsistent with the company's own statements from earlier this year explaining why people use Ariva. Moreover, even assuming that Star is correct when it takes this new position, Star's reliance on Nutrilab is based on an unduly narrow reading of the law.

1. Star May Now Take a Different Position, but it Has Previously Conceded That Ariva is Used by Consumers for Taste.

While Star now claims that people do not use Ariva for its taste, that is not what Star was saying about the product just nine months ago before these regulatory proceedings commenced. At that time, Star indicated that individuals do use Ariva for its taste. For example:

- In December 2001, Star's Chairman and President stated that "Ariva is used by adult smokers to get tobacco taste and satisfaction when they cannot smoke" (emphasis added).³
- In January 2002, on the basis of its own marketing studies, Star reported: "[a]s we learned in our initial focus groups and surveys, Ariva is being chosen by long-term adult smokers because of its taste, tobacco satisfaction, and convenience for a variety of occasions when they can't smoke" (emphasis added).⁴
- "Star Scientific believes Ariva smokeless cigarett pieces provide adult smokers, for the first time, with the opportunity to choose a convenient, taste-

2 See Star Scientific's Comments Concerning Citizen Petition for Regulation of Ariva 7 (May 1, 2002) (Docket No. 02P-0075); Star Scientific's Response to GSK Comments 2 (Aug. 16, 2002) (Docket Nos. 01P-0572 and 02P-0075).

3 See Press Release, Star Scientific, Inc., Paul L. Perito, Chairman, President and Chief Operating Officer of Star Scientific, Inc. Today Issued the Following Statement (Dec. 19, 2001) (attached as Exhibit L to GSK's Citizen Petition of Feb. 15, 2002).

4 See Press Release, Star Scientific, Inc., Star Scientific, Inc. Issues Statement on Ariva Test Marketing, Fourth Circuit Opinion (Jan. 23, 2002) (attached as Exhibit C to GSK's Citizen Petition of Feb. 15, 2002).

Dockets Management Branch, FDA
October 1, 2002
Page 4 of 23

acceptable alternative to use in all those environments where smoking is prohibited either by law or social custom” (emphasis added).⁵

- “Star believes Ariva will be the first hard smokeless tobacco product to be developed in the U.S. that is both taste-acceptable and responsive to the needs of adult smokers who want an alternative to cigarettes in the many smoke-free environments they confront on a daily basis” (emphasis added).⁶

And, while Star may adamantly dispute the fact that the product tastes like candy, that is not how others (including two Internet tobacco distributors) have described it.⁷ The Discount Cigarettes Shopping Guide Newsletter – an industry periodical published on the Internet – recently sampled Ariva and endorsed concerns about keeping the product away from children since “the stuff [Ariva] tastes like candy, although probably a little strong for young kid’s tastes.”⁸ In sum, given such descriptions and Star’s own statements and studies, Ariva is a food product under the Nutrilab standard.

2. Star’s Reliance on the Nutrilab Decision Is Misplaced Since That Case Involved Interpretation of The Term “Food” in Section 321(g) of the FDCA – a Provision That Is Not At Issue In This Proceeding.

To complete its argument that Ariva is not a food under the FDCA, Star asserts that Nutrilab controls determinations by FDA of what constitutes a food under the FDCA.⁹ Pointing to the FDA’s recent decision involving Nicotine Water, Star claims that

5 See Press Release, Star Scientific, Inc., Star Scientific Announces Test Market for Ariva Smokeless Tobacco Cigarettes; Test Markets Initiated in Dallas, Texas and Richmond, VA (Nov. 14, 2001) (attached as Exhibit I to GSK’s Citizen Petition of Feb. 15, 2002).

6 See Press Release, Star Scientific, Inc., Star Scientific and B&W Enter Into Contracts for Purchases of Starcured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products (Apr. 27, 2001) (attached as Exhibit E to GSK’s Citizen Petition of Feb. 15, 2002).

7 Although sales of Ariva from these sites have now been discontinued, the product was advertised there as being “very similar in taste to an Altoid mint.” See GSK’s Letter Regarding Internet Sales of Ariva 3 (June 14, 2002) (Docket Nos. 01P-0572 and 02P-0075).

8 See Discount Cigarettes Shopping Guide Newsletter (May 2002), available at <http://www.discount-cigarettes.org/may31nl.html> (excerpts attached as Exhibit B).

9 Star also overstates the test adopted by the Nutrilab court. The Court of Appeals expressly rejected the District Court’s conclusion that a food product under Section 321(g)(1)(C) is one used “solely” for taste, aroma, or nutritive value. Rather, the Court of Appeals used the word “primarily” rather than “solely” since certain products, such as coffee, are “undoubtedly food but

Dockets Management Branch, FDA

October 1, 2002

Page 5 of 23

FDA “uses the Nutrilab analysis” for such purposes. Star is incorrect. In Nutrilab, the court considered the question whether “starch blockers” should be treated as “drugs” or “foods” under the FDCA. The FDA took the position that such products were drugs that could not be marketed until Nutrilab and other manufacturers received approval from the agency. To avoid this result, Nutrilab argued that starch blockers are foods and, therefore, are expressly excluded from the definition of the term drug under the Act. In support of this argument, Nutrilab invoked Section 201(g)(1)(C) of the FDCA, which provides that “the term drug means . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals.” 21 U.S.C. § 321(g)(1)(C) (emphasis added). Thus, to resolve the regulatory status of starch blockers, the court was required to decide the meaning and breadth of the phrase “other than food” contained in Section 201(g)(1)(C). This was, of course, precisely the same inquiry before FDA when it reached its decision about Nicotine Water.¹⁰

It is in this context that the Nutrilab court’s interpretation of the statutory definition of food, and FDA’s reliance on that analysis, must be viewed. Indeed, the Nutrilab case was not about whether a product was to be considered a food or whether it was going to be unregulated, as is the situation here. The question in Nutrilab was which regulatory regime should apply: the relatively unrestrictive food provisions, or the much more restrictive regulatory scheme governing drugs. In answering that question, the Court of Appeals implicitly, and the District Court explicitly, construed the parenthetical exemption for food “mindful of the policy requiring liberal construction of the terms consistent with the overriding purpose of the Act – the protection of public health.”¹¹ Since the FDCA establishes more stringent requirements governing drugs than foods, the Nutrilab court construed the term “food” so that the exemption in Section 321(g)(1)(C) is a very narrow one. Accordingly, when the Nutrilab court fashioned its test, it enunciated a narrow standard to ensure that questionable products are treated as drugs before foods.¹²

may be consumed on occasion for reasons other than taste, aroma, or nutritive value.” See Nutrilab, 713 F.2d at 338.

10 See Letter From Dennis E. Baker, Associate Commissioner for Regulatory Affairs, FDA, to William B. Schultz, Zuckerman Spaeder LLP (July 1, 2002) (attached as Exhibit C).

11 See Nutrilab, Inc. v. Schweiker, 547 F. Supp. 880, 882 (N.D. Ill. 1982); American Health Products v. Hayes, 574 F. Supp. 1498, 1503 (S.D.N.Y. 1983) (“American Health Products”) (“like others designed to protect the public health, [the FDCA] should be liberally construed to advance that purpose”).

12 This result is entirely consistent with the legislative history surrounding this provision. The original Food and Drug Act, enacted in 1906, only classified articles intended for the treatment of disease as drugs. Under this definition, certain products, including “anti-fat remedies” marketed with claims of “slendering effects” escaped regulation since obesity (at least then) was not considered a disease. To address this problem, Congress added what became Section

Dockets Management Branch, FDA
October 1, 2002
Page 6 of 23

That standard, however, was not meant to restrict the broad definition of the term “food” in Section 201(f) adopted by other courts over the years.¹³ And, FDA has not limited its interpretation of Section 201(f) based on the Nutrilab decision.¹⁴ In fact, as described next, FDA did not use the Nutrilab test when it found five years after that decision that another tobacco-containing food product – Masterpiece Tobacs – is a food under the FDCA.

B. As FDA Concluded in the Masterpiece Tobacs Case, the FDCA’s Definition of Food in Section 321(f) is Expansive and it Includes Products Containing Tobacco Such As Ariva When They Are Sold in Food Form.

Star next challenges GSK’s analysis demonstrating that Ariva is subject to the FDCA because it is sold in food form. To that end, Star argues that Ariva must be a tobacco product because, when “crushed, it produces exactly the same product as Stonewall dry snuff, and the crushed Ariva cigarette has exactly the same appearance, color and graininess throughout.” Yet, Ariva is obviously not being sold in crushed form and, in any event, the statutory term “food” is not to be defined in terms of the “biochemical composition” of the product. Nutrilab, 713 F.2d at 337. Rather, as FDA recognized in the Masterpiece Tobacs decision, the “test for determining whether an item is a food under the Act . . . must of necessity be one which regards items as foods which

201(g)(1)(C) to expand the reach of the drug definition to encompass “a great many products that have been found on the market that cannot be alleged to be treatments for diseased conditions.” See Nutrilab, 713 F.2d at 336 citing 1 Legislative History of Food, Drug and Cosmetic Act 105, 107-08. Nowhere in the legislative history in there any suggestion that Congress sought to narrow the broad definition of food in Section 201(f) in connection with this amendment.

13 The courts have expressly recognized that the two definitions of food in the two statutory provisions are distinct. See, e.g., American Health Products, 574 F. Supp. at 1504 (“meaning of the term food for purposes of the parenthetical exclusion [of Section 321(g)(1)(C)] and its technical statutory meaning [under Section 321(f)] for purposes of coverage of the food provisions cannot be identical”); United States v. Nature’s Bounty, Inc., 888 F. Supp. 381, 391 (E.D.N.Y. 1995) (“the common-use meaning given to the term ‘food’ in the parenthetical exclusion of Section 321(g)(1)(C) and in Section 321(f)(1) is more circumscribed and not identical to the statutory meaning of food under Section 321(f)”).

14 When FDA considered the arguments of Pinkerton Tobacco (“Pinkerton”) in the Masterpiece Tobacs case, it found that the legislative history involving the distinctions between a drug and food under Section 321(g)(1)(C) is “not relevant” to the question whether a product is a food or is not subject to regulation under the FDCA at all. See Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA, to Stuart Pape, Patton, Boggs & Blow (Apr. 12, 1988) (attached as Exhibit A to GSK’s Letter of July 11, 2002, Responding to Star Scientific’s Comments).

Dockets Management Branch, FDA
October 1, 2002
Page 7 of 23

are generally so regarded when sold in food form." United States v. Technical Egg Products, Inc., 171 F. Supp. 326, 328 (N.D. Ga. 1959) (emphasis added). And, as FDA concluded after that decision, the "ingestibility" of a product can be an important factor in determining whether a particular article is a food.¹⁵ Applying that standard here, Ariva constitutes a food product under Section 321(f) of the FDCA.

1. Ariva Possesses the Characteristics of a "Product Sold in Food Form" That FDA Specified in the Masterpiece Tobacs Case.

As GSK previously explained in great detail,¹⁶ FDA specified at least six factors that led it to decide that Masterpiece Tobacs is a food under the FDCA because it is sold in "food form." As set forth below, Star has not filed any evidence in the record to refute the fact that Ariva possesses many of the same key characteristics and, therefore, is also a product being sold in food form.

- *Unlike Traditional Tobacco Products:* GSK submitted information in the docket on February 15, 2002, and July 11, 2002, demonstrating that Star has specifically sought to distinguish Ariva from other traditional tobacco products in the marketplace by describing it as "ground-breaking," "innovative," and a "flagship" product.¹⁷
- *Candy-Like Appearance:* Ariva has almost universally been described and viewed as a candy-like product that closely resembles a Tic Tac® in appearance. GSK submitted this information to FDA in its July 11, 2002, letter.¹⁸

15 Despite seemingly contrary language in Nutrilab, 713 F.2d at 337, that position was upheld in United States v. Nature's Bounty, Inc., 888 F. Supp. at 396 ("ingestibility [is] a functional factor when determining whether a particular article is a food" since "ingestion has everything to do with the common place and everyday meaning of 'food'").

16 See GSK's Response to Star Scientific's Comments Opposing Citizen Petitions for Regulation of Ariva 3 (July 11, 2002) (Docket Nos. 01P-0572 and 02P-0075); see also GSK's Letter Regarding Composition of Ariva 2 (Apr. 26, 2002) (Docket Nos. 01P-0572 and 02P-0075).

17 See, e.g., Press Release, Star Scientific Inc., Star Scientific Announces Test Market of Ariva Smokeless Tobacco Cigarettes; Test Markets Initiated in Dallas, Texas and Richmond, VA (Nov. 14, 2001) (attached as Exhibit I to GSK's Citizen Petition of Feb. 15, 2002); Press Release, Star Scientific, Inc., Star Scientific And B&W Enter Into Contracts for Purchases Of StarCured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products (Apr. 27, 2001) (attached as Exhibit E to GSK's Citizen Petition of Feb. 15, 2002).

18 See GSK's Response to Star Scientific's Comments Opposing Citizen Petitions for Regulation of Ariva 2-3 (July 11, 2002) (Docket Nos. 01P-0572 and 02P-0075).

Dockets Management Branch, FDA
October 1, 2002
Page 8 of 23

- *Food Ingredients:* While Ariva may not contain a masticatory carrier base like Tobacs, it does consist of other standard constituents of food (e.g., polymers, buffering agents, pH modifiers, anti-oxidants, emulsifiers) designed to prolong the disintegration and dissolution times of each candy-like unit. GSK filed this information in the record on April 26, 2002.¹⁹
- *Flavors and Sweeteners:* In its letters of May 1, 2002, and August 16, 2002, Star concedes that Ariva contains sugars, mint, eucalyptus, and other natural and artificial flavorings and ingredients.²⁰ Such ingredients are obviously designed to encourage ingestion since Ariva is not meant to be expectorated.
- *Discrete Shape:* Like other candy products, Ariva is shaped and sold in a discrete form – an elongated oval.
- *Outer Coloring:* The exterior surface of Ariva appears in a brownish color. Star does not challenge this fact, but it contends that this description is misleading because Ariva does not have a chocolate or candy outer coating. Star misses the point; FDA mentioned this factor because it was concerned that Masterpiece Tobacs had the appearance of chocolate – not that it actually contained chocolate.²¹

Since Ariva satisfies FDA's criteria for defining a product sold in food form, it too is subject to FDA's jurisdiction as a food product. Of course, as the state Attorneys General pointed out in their submission to FDA, that conclusion is reinforced by the fact that Ariva is also packaged in a manner that suggests it could be a food product (e.g., blister packs for each unit like certain chewing gums, packaging contains images of blue sky and clean water).²² Moreover, while there is evidence in the record indicating that

19 See GSK's Letter Regarding Composition of Ariva 2 (Apr. 26, 2002) (Docket Nos. 01P-0572 and 02P-0075).

20 See Star Scientific's Comments Concerning Citizen Petition for Regulation of Ariva 2-3 (May 1, 2002) (Docket No. 02P-0075); Star Scientific's Response to GSK Comments 3-4 (Aug. 16, 2002) (Docket Nos. 01P-0572 and 02P-0075).

21 Of course, it does not make a difference that Ariva does not have a candy outer coating. Other products, including Altoids® and Pez®, also do not have an outer coating, but obviously are considered candies and foods by the FDA under the FDCA.

22 See State Attorneys General's Comments in Support of Citizen Petitions for Regulation of Ariva 6 (July 16, 2002) (Docket Nos. 01P-0572 and 02P-0075).

Dockets Management Branch, FDA
October 1, 2002
Page 9 of 23

Ariva is being placed on shelving near drug products designed to help smokers stop smoking,²³ Ariva has also appeared from time to time in a front counter display immediately above the shelving for gums and candies.²⁴

2. Star Cannot Distinguish FDA's Decision Involving Masterpiece Tobacs Since the Agency Focused Broadly on the Totality of the Product and Not on Just the Fact that it Was a Chewing Gum.

Star has also sought to distinguish the Masterpiece Tobacs decision by arguing that Tobacs was a chewing gum – a product that is expressly defined in the statutory definition of food. 21 U.S.C. § 321(f)(2). An analysis of the administrative record in the case, however, makes clear that FDA did not base its decision on that fact. In its letter appealing the decision of the Center for Food Safety and Applied Nutrition, Pinkerton argued that the fact that Masterpiece Tobacs contained a masticatory substance did not necessarily make it a chewing gum and, consequently, a food for the purposes of the FDCA.²⁵ In response, FDA indicated that Masterpiece Tobacs differs from conventional portion-packed snuff not because it uses a masticatory carrier base but rather because it satisfied the agency's broader criteria for defining a product that is sold in food form. And, it was on the basis of these criteria – not just inclusion of a masticatory carrier base – that FDA concluded that Masterpiece Tobacs is a food product.²⁶

It would be particularly troubling if FDA were to distinguish Ariva from Masterpiece Tobacs on these grounds because inclusion of “chewing gum” in the statutory definition of food was meant to broaden the agency's jurisdiction over foods – not limit it. The definition of food in the FDCA was modified in 1938 and it has

23 See Campaign for Tobacco Free Kids' Letter Supplementing Its Citizen Petition For Regulation of Ariva (June 24, 2002) (Docket No. 01P-0572).

24 See Photographs Attached as Exhibit D.

25 See Letter from Stuart M. Pape, Counsel to Pinkerton Tobacco Company, Patton, Boggs & Blow, to John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA 14-17 (Dec. 1, 1987) (attached as Exhibit E).

26 To drive this point home, FDA expressly indicated that it was exercising jurisdiction over Tobacs since it “has the appearance of a piece of gum . . . or of candy” and it “looks, tastes, and chews like chewing gum or a confection” (emphasis added). See Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA, to Stuart Pape, Patton, Boggs & Blow (Apr. 12, 1988) (attached as Exhibit A to GSK's Letter of July 11, 2002, Responding to Star Scientific's Comments).

Dockets Management Branch, FDA

October 1, 2002

Page 10 of 23

remained unchanged since that date.²⁷ In connection with those amendments, Congress made clear that it was expanding the definition of food to eliminate any doubt that the Act governs chewing gum products and ingredients that are used in food.²⁸ Although the legislative history does not further clarify the questions raised about chewing gum, it is likely that chewing gum was expressly included in the definition of food to ensure that FDA could regulate products which are not entirely consumed or digested. Hence, if Congress amended the statute to encompass such products, it would be anomalous for FDA to conclude that Congress did not also intend for the agency to regulate candy-like products containing tobacco like Ariva which are entirely consumed and digested.

C. **Nothing in the Brown & Williamson Decision Undermines FDA's Sweeping Authority to Regulate Ariva As An Adulterated Food Product Under the FDCA.**

In its earlier submissions to FDA, GSK also explained in great detail why FDA's decision on its citizen petition is not governed by the Supreme Court's holding or rationale in Brown & Williamson. To summarize, that case does not apply for, at least, the following reasons:

- *Different Statutory Scheme:* GSK is asking FDA to regulate Ariva under an entirely different regulatory scheme than that at issue in Brown & Williamson. Star concedes that Brown & Williamson did not address the question whether food products containing tobacco are subject to FDA's regulation under the food provisions of the FDCA. Star only relies on the "reasoning" of the court to "compel" its conclusion that FDA is without jurisdiction.²⁹

27 The 1906 Act defined "food" as including "all articles used for food, drink, confectionary, or condiment by man or other animals, whether simple, mixed, or compound." Federal Food and Drugs Act of 1906, Ch. 3915, 34 Stat. 768, 769. One court considering this definition has remarked that the 1906 Congress "did not appear to be particularly concerned with limiting or restricting the definition of food." See United States v. Tunte Livestock, 888 F. Supp. 1416, 1423 (D. Ohio 1995).

28 See Hearing on S. 5 before a Subcommittee of the House Committee on Interstate and Foreign Commerce, 74th Cong. (1st Session, July 22-Aug. 12, 1935), reprinted in 4 Legislative History of the Food, Drug, and Cosmetic Act and its Amendments 370. "The definition of 'food' . . . is identical to that in the present act except that it eliminates any doubt as to whether or not chewing gum and ingredients entering into food, like baking powder, were or were not food. Such questions have been raised in the past. So this definition provides for those products as foods." (statement by Walter G. Campbell, Chief of the Food and Drug Administration).

29 See Star Scientific's Comments Concerning Citizen Petition for Regulation of Ariva 10 (May 1, 2002) (Docket No. 02P-0075).

Dockets Management Branch, FDA
October 1, 2002
Page 11 of 23

- *No Statutory Conflict:* Under the FDCA's regulatory scheme governing foods, no fatal or irreconcilable conflict exists that, as with the drug provisions, would automatically preclude marketing of a "smokeless tobacco product" under the CSTHEA. Star concedes that Ariva could reach the market if FDA determines that its tobacco can be safely marketed as a food additive, but it argues that it need not await the result of that decision-making process.³⁰
- *Safer Product:* In Brown & Williamson, the court found that traditional tobacco products could not be regulated as drugs and medical devices since substantial scientific evidence "exhaustively documented" that they are "unsafe" and "dangerous" products. To the extent that this rationale applies to the FDCA's provisions governing foods, FDA regulation of Ariva is not automatically precluded since Ariva has been designed to be a safer tobacco product. Star denies that it has claimed that Ariva is safer than other tobacco products, but the record suggests otherwise.³¹
- *Jurisdictional Position:* The Supreme Court was clearly influenced by FDA's numerous statements over the years that it lacked jurisdiction over cigarettes and smokeless tobacco products under the drug provisions of the FDCA. In contrast, FDA has taken the position that it maintains jurisdiction over food products containing tobacco under those provisions of the FDCA governing food.³²

30 See Star Scientific Comments Concerning Citizen Petition for Regulation of Ariva 18 (May 1, 2002) (Docket No. 02P-0075).

31 See infra Part C.3.

32 To be sure, FDA's Bureau of Enforcement issued a letter in 1963 stating that tobacco marketed for chewing or smoking without therapeutic claims does not meet the FDCA's definitions of food, drug, device or cosmetic. See Memorandum from Bureau of Enforcement to Directors of Bureaus and Divisions and Directors of Districts, Tobacco Products Without Therapeutic Claims (May 24, 1963) (attached as Exhibit F). Even Star must concede, however, that this interpretation of the FDCA as it applies to food is incorrect since the definition of food under the Act does not turn on claims made about the product. See American Health Products, 574 F. Supp. at 1505 (it is "the ordinary way in which an article is used [and] therefore, not any marketing claim on the part of the manufacturer or distributor as to specific physiological purpose of that use, [that] should determine whether it is a food for the purpose [of the FDCA]"); United States v. Nature's Bounty, 888 F. Supp. 381, 391-392 (E.D.N.Y. 1995) (although the intent of the vendor may be "a key element" in determining whether a product constitutes a "drug" under the FDCA, "that is not the case . . . with regard to determining whether a product is a food").

Dockets Management Branch, FDA
October 1, 2002
Page 12 of 23

- *Regulatory Consequences:* The Brown & Williamson court found that the simple exercise of jurisdiction by FDA over traditional tobacco products as “drugs” was not possible since it would require removal of such products from the market. That result is not foreordained here. GSK is only asking FDA to require Star to file a food additive petition for Ariva. That action does not immediately preclude marketing of Ariva and, as Star admits, could allow for it.
- *Traditional Tobacco Products:* As a matter of law, the court’s decision only encompasses “smokeless tobacco products” that are subject to the “tobacco specific legislation” (i.e., CSTHEA) considered in the first place. While FDA need not decide that Ariva is outside the scope of that statute to regulate Ariva (since no statutory conflict exists between the CSTHEA and FDCA), Ariva is obviously not the type of traditional tobacco product contemplated by the court.

Despite these important differences, Star once again selectively extracts broad language from the Brown & Williamson decision in the hope that it can extend that court’s holding about the drug and medical device provisions of the FDCA to the instant case. As set forth below, none of Star’s arguments is helpful.

1. The Plain Language of the FDCA Demonstrates that Congress Has Recognized that Foods Containing Tobacco Are Subject to FDA’s Jurisdiction

Star continues to assert that Brown & Williamson stands for the proposition that Congress has simply forbidden FDA from exercising jurisdiction over any product containing tobacco under any provision of the FDCA (unless therapeutic claims accompany the product). In support of this proposition, Star relies heavily on the Supreme Court’s finding that FDA had repeatedly advised Congress that it did not have jurisdiction to regulate “customarily marketed” tobacco products under the FDCA and that Congress had rejected proposals to give FDA that authority. Yet, to the extent that Congress has addressed the narrower question whether FDA maintains jurisdiction over food products containing tobacco, an analysis of the FDCA demonstrates that Congress has not stripped FDA of its authority over such products. Star, therefore, cannot sweep the instant case away by invoking the Brown & Williamson decision.

In 1987, a key member of Congress requested FDA to provide a “description of the extent and limits of the agency’s authority over food and drug products containing

Dockets Management Branch, FDA
October 1, 2002
Page 13 of 23

nicotine,”³³ In response to that inquiry, FDA distinguished its jurisdictional position on “traditional tobacco-containing products, as customarily marketed” from food products containing tobacco. As to the former category, which was defined to include “smoking tobacco, cigarettes, cigars, chewing tobacco, and snuff,” FDA indicated that it did not have jurisdiction unless health claims accompanied such products. On the other hand, and citing the *Masterpiece Tobacs* decision, the agency advised Congress that it did have authority to regulate certain products containing tobacco as foods under the FDCA.³⁴ Thus, while *Star* has sought to make much of the Supreme Court’s use of the term “customarily marketed” tobacco product, FDA had previously and expressly excluded foods containing tobacco from that phrase. And, at least as of 1987, Congress has been on notice of FDA’s position that the agency has jurisdiction to regulate certain products containing tobacco as foods and that tobacco can be treated as an unapproved food additive under the FDCA.

For the purposes of statutory construction, Congress can be presumed to have knowledge of FDA’s interpretation of the FDCA to govern foods containing tobacco.³⁵ That is significant because Congress did not undermine or in any way disturb that authority when it adopted amendments to the FDCA in 1994 bearing directly on FDA’s authority to regulate tobacco under the food provisions of the FDCA. Specifically, with enactment of the Dietary Supplement Health and Education (“DSHEA”), Congress defined the term “dietary supplement” as a “product (other than tobacco) intended to supplement the diet.” 21 U.S.C. § 321(ff)(1). At the same time, Congress amended the definition of the term “food additive” to exclude any product falling within the definition of “dietary supplement.” 21 U.S.C. § 321(s)(6). These amendments demonstrate that: (1) Congress implicitly recognized that the term “food” could include products containing tobacco since otherwise there would have been no need to exclude tobacco from the term dietary supplement – a subset of foods³⁶; and (2) Congress did not intend

33 See Letter from Henry A. Waxman, Chairman, Subcommittee on Health and the Environment, to Frank Young, Commissioner, FDA (July 1, 1987) (attached as Exhibit G).

34 See Letter from Frank E. Young, Commissioner of Food and Drugs, FDA, to Henry A. Waxman, Chairman, Subcommittee on Health and the Environment (Sept. 29, 1987) (attached as Exhibit H).

35 See, e.g., *Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) (“Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. So too, where, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute”).

36 The FDCA declares that “a dietary supplement shall be deemed to be a food within the meaning of this chapter.” 21 U.S.C. § 321(ff).

Dockets Management Branch, FDA
October 1, 2002
Page 14 of 23

for tobacco to escape regulation as an unapproved food additive by being characterized as a dietary supplement. Therefore, far from depriving FDA of authority to regulate foods containing tobacco, Congress must be viewed as acting to preserve FDA's power to act in this manner.³⁷

2. The Preemption Provision in the CSTHEA Only Governs Labeling and Advertising, and it Does Not Preclude FDA From Regulating the Composition of Ariva under the FDCA.

Star also continues to rely on Section 7 of the CSTHEA, 15 U.S.C. § 4406(a), for the proposition that Congress has expressly prohibited FDA from regulating foods containing tobacco under the FDCA. Star goes much too far. Indeed, it disregards the decision of the Court of Appeals for the First Circuit where a substantially identical preemption provision in the CSTHEA was very narrowly construed. See Philip Morris, Inc. v. Harshbarger, 122 F.3d 58, 77-78 (1st Cir. 1997) (finding that CSTHEA does not invalidate a Massachusetts law requiring tobacco product manufacturers to disclose the ingredients and nicotine yield ratings for each product sold there).³⁸ At the same time, Star ignores FDA's earlier conclusion in the Masterpiece Tobacs case where Pinkerton made precisely the same arguments and the agency declared that "there is nothing in this preemption provision that would preclude FDA from regulating the composition of a smokeless tobacco product in appropriate circumstances."³⁹ Thus, the labeling preemption provision in the CSTHEA does not prevent FDA from regulating Ariva – at most, it would only bar FDA from requiring additional health statements on the packaging or in advertisements involving Ariva.

37 Moreover, Congress did not undermine FDA's authority to regulate foods containing tobacco when it enacted the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997) (law "shall [not] be construed to affect the question of whether the [FDA] has any authority to regulate any tobacco product," and "such authority, if any, shall be exercised under the [FDCA] as in effect on the day before the date of [this] enactment"). See Note Following 21 U.S.C. § 321.

38 See also Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) (finding that a similar provision in the Federal Cigarette Labeling and Advertising Act does not bar state or federal regulation outside the provision's literal scope).

39 See Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA, to Stuart Pape, Patton, Boggs & Blow (Apr. 12, 1988) (attached as Exhibit A to GSK's Letter of July 11, 2002 Responding to Star Scientific's Comments).

Dockets Management Branch, FDA
October 1, 2002
Page 15 of 23

3. Although Star Argues that Brown & Williamson Precludes FDA Regulation Of Ariva For the Same Reasons As Traditional Tobacco Products, Star Has Repeatedly Portrayed Ariva as a Safer Product.

To sweep its product into the Brown & Williamson decision, Star also persists in its argument that it has never claimed that Ariva is “safer” than other traditional tobacco products. Instead, Star contends that it has “repeatedly stated” that “there is no proof that reducing TSNAs in Ariva will lead to a reduction in the health risk” and “additional studies need to be done to determine” whether a reduction of TSNAs reduces the risk of oral cancer. As the sampling below makes clear, however, Star has made numerous statements during the past three years where it all but declares that Ariva is “safer” than other tobacco products.

- “We are understandably proud of what we have accomplished in consistently producing flue-cured tobacco with dramatically reduced toxin levels. It has been our intent from the outset to encourage the industry to adopt this standard, which we believe reduces exposure to tobacco-related diseases”⁴⁰
- “. . . Ariva(TM) contains almost undetectable levels of tobacco-specific nitrosamines (TSNAs), which reputable scientists believe are the only biologically significant carcinogens in smokeless tobacco. The TSNA levels in Ariva(TM) are approximately one one-hundredth of the levels found in the best-selling smokeless tobacco products”⁴¹
- “Many researchers believe that TSNAs may be the most significant, if not the only significant, carcinogens in conventional smokeless tobacco. In contrast to conventional smokeless products, our moist snuff product, Stonewall(TM), and our compressed hard-snuff product, ARIVA(TM), will have TSNA levels that are more than 95% lower than those in conventional snuff products currently sold in the United States.”⁴²

40 See Press Release, Star Scientific, Inc., Federal Court Dismisses Philip Morris Lawsuit That Challenged Star Scientific Patent for Reducing Cancer-Causing Toxins (Sept. 12, 2002) (attached as Exhibit I).

41 See Press Release, Star Scientific, Inc., Star Scientific, Inc. Comments on State Attorney Generals’ FDA Submission (July 17, 2002) (attached as Exhibit J).

42 See Press Release, Star Scientific, Inc., Star Scientific Applauds Canadian Tobacco Regulations, Virginia’s “No ID, No Tobacco” Initiative; Receives BATF License for Chase City Ariva Manufacturing Facility (July 3, 2001) (attached as Exhibit K).

Dockets Management Branch, FDA
October 1, 2002
Page 16 of 23

- “The tobacco specific nitrosamines (of which NNNs and NNKs are the most carcinogenic) are acknowledged by leading medical and scientific researchers to be among the most potent and abundant cancer-causing toxins in tobacco and tobacco smoke.”⁴³
- “This proprietary StarCured(TM) process virtually precludes and/or substantially reduces the formation in the tobacco leaf of the carcinogenic TSNAs, which are widely believed by medical and scientific experts to be among the most potent and powerful cancer-causing toxins present in tobacco and in side stream tobacco smoke.”⁴⁴
- “There is a substantial difference between the numbers and levels of toxic constituents in smoked, and in smokeless tobacco products. There are 4,000 chemical constituents in tobacco smoke, 43 of which are known or suspected carcinogens. Smokeless tobacco, however, is not burned and therefore the user is exposed to many fewer carcinogens. Public health authorities have determined that there are only a handful of toxins that are of concern in smokeless tobacco, and of this handful only the nicotine and TSNA’s appear to be at levels that are likely linked to health problems.”⁴⁵

Moreover, while Star has in certain instances qualified such statements, it has not always done so in the unequivocal manner that its August 16, 2002, letter suggests. Nor has Star’s qualifying statements always been included in the document or press release where Star suggests that Ariva consists of safer tobacco (including the statements outlined above). A representative sample of Star’s “other caveats” about TSNAs follows:

- “Although it may take time for our company or independent researchers to obtain evidence that a reduction in TSNAs translates into a reduction in risk, we believe there is no valid reason, in light of the development of the

43 See Press Release, Star Scientific, Inc., Star Scientific Inc. Files Suit Against R.J. Reynolds to Enforce Patent For Curing Tobacco to Substantially Prevent the Formation of Cancer-causing Tobacco Specific Nitrosamines (TSNAs) (May 24, 2001) (attached as Exhibit L).

44 See Star Scientific, Inc., Annual Report for 1999 (SEC Form 10-K) (Dec. 31, 1999) (pertinent sections attached as Exhibit M).

45 See Star Scientific, Inc., WHAT IS ARIVA™?, Star Scientific Comments Concerning Citizen Petition for Regulation of Ariva (May 1, 2002) (Attachment 3) (Docket No. 02P-0075).

Dockets Management Branch, FDA
October 1, 2002
Page 17 of 23

StarCured™ technology, for tobacco users to continue to be exposed to these toxins.”⁴⁶

- “. . . the Company in discussing its low-TSNA products has shared with adult consumers the fact that there is not now sufficient evidence to demonstrate that reduced toxin delivery can be quantified in terms of reduced health risk.”⁴⁷
- “We are committed to working with public health officials, scientists and regulators in an effort to determine whether the removal of TSNA’s will reduce the incidence of cancer. Although it may take years to secure this evidence, we believe there is no valid reason, in light of our available technology, for smokers or nonsmokers to continue to be exposed to these particular carcinogens.”⁴⁸

In light of Star’s own statements about Ariva and how it is different from traditional tobacco products on the basis of safety, Star cannot seriously claim that Brown & Williamson controls the issues before FDA. Rather, as Star suggests in the last quote cited above, the company must now fulfill its commitment to study TSNA’s by working with FDA pursuant to the food additive petition process to determine whether the tobacco in Ariva can be safely consumed.

D. The FDA Need Not Determine That Ariva is Not a “Smokeless Tobacco Product” Under the CSTHEA to Grant GSK’s Petition.

Star also confuses the issues before FDA by continuing to place great emphasis on its argument that Ariva is a smokeless tobacco product for the purposes of the CSTHEA. As GSK emphasized in its petition and subsequent filings, FDA does not need to address or resolve this question in order to grant GSK’s petition. That is because Ariva can simultaneously be regulated by FDA under the FDCA and the FTC under the CSTHEA. In addition, the agency cannot rely on Star’s claims that Ariva is like other

46 See Star Scientific, Inc., About Star Scientific, Inc., *available at* <http://www.starscientific.com> (attached as Exhibit N).

47 See Star Scientific, Inc., Annual Report for 2001 (SEC Form 10-K) (Dec. 31, 2001) (pertinent sections attached as Exhibit O).

48 See Statement by Paul L. Perito to the Framework Convention on Tobacco Control of the World Health Organization (Sept. 21, 2000), *available at* <http://www.starscientific.com> (attached as Exhibit P).

Dockets Management Branch, FDA
October 1, 2002
Page 18 of 23

conventional smokeless tobacco products in the marketplace and is, therefore, not a food product under the FDCA.

1. Regulation of Ariva as a “Smokeless Tobacco Product” by the FTC and BATF Under Tobacco-Specific Legislation Does Not Preclude FDA From Exercising Jurisdiction over the Product As a “Food” Pursuant to the FDCA.

Star claims that Ariva cannot be a food product under the FDCA since the product is treated by the Federal Trade Commission (“FTC”) and the Bureau of Alcohol, Tobacco and Firearms (“BATF”) as a smokeless tobacco product under the CSTHEA and other federal statutes governing tobacco products (e.g., 26 U.S.C. § 5710).⁴⁹ As GSK previously explained in its July 11, 2002, letter supplementing the docket, this argument is without merit. That is because no statutory conflict arises from dual regulation of Ariva as a food under the FDCA and as a smokeless tobacco product under the CSTHEA and other tobacco-specific statutes. The FDA, FTC, and BATF have previously agreed that a food product containing tobacco (i.e., Masterpiece Tobacs) could simultaneously be regulated under these statutes.⁵⁰ The agencies reached that decision shortly following enactment of the CSTHEA and, as described above, nothing in Brown & Williamson alters this conclusion. Here, no such conflict exists and it is highly unlikely that any court considering this issue would rule otherwise.⁵¹

49 Star’s reliance on the BATF and FTC for this proposition is disingenuous since the company openly invited those agencies to exercise jurisdiction over Ariva in this manner. Star presents no evidence indicating that either agency considered Ariva’s status as a food product under the FDCA when it authorized Star to manufacture and market Ariva under those statutes governing smokeless tobacco products.

50 See Letter from Richard Ronk, Acting Director, Center for Food Safety and Applied Nutrition, FDA, to Stuart Pape, Patton, Boggs & Blow (Sept. 16, 1987) (attached as Exhibit J to GSK’s Citizen Petition of Feb. 15, 2002); Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA, to Stuart Pape, Patton, Boggs & Blow (Apr. 12, 1988) (attached as Exhibit A to GSK’s Letter of July 11, 2002, Responding to Star Scientific Comments).

51 It is well-established that, when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective. See, e.g., St. Martin Evangelical Lutheran Church v. South Dakota, 451 U.S. 772, 788 (1981); United States v. Borden Co., 308 U.S. 188, 198 (1930). At the same time, the courts would be especially deferential to the position that FDA, FTC and BATF took on this issue shortly following passage of the CSTHEA. See, e.g., General Electric Co. v. Gilbert, 429 U.S. 125, 142-143 (1976) (assigning little weight to an agency’s statutory interpretation which “flatly contradicted” the position previously articulated by the agency); Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 414 (1993) (“Of particular relevance is the agency’s contemporaneous

Dockets Management Branch, FDA
October 1, 2002
Page 19 of 23

2. Based On Star's Own Description of Ariva, and Given the Absence of Similar Products on the Market, Ariva Cannot be Considered a Conventional Smokeless Tobacco Product.

In its press releases and other literature, Star has consistently sought to distinguish Ariva from other traditional smokeless tobacco products in the marketplace. For example, Star has described Ariva as:

- “. . . a new, smokeless hard tobacco product, a ‘cigalett’, that will not have the unpleasant aesthetics associated with conventional moist snuff and chewing tobacco.”⁵²
- “. . . an exciting innovation that will maintain the company's leadership in transforming the conventional tobacco industry . . . ”⁵³
- “. . . a groundbreaking hard tobacco ‘cigalett’ . . . ” and a “. . . flagship smokeless tobacco product . . . ”⁵⁴
- “. . . an innovative smokeless tobacco product that neither requires smoke to be inhaled into the lungs nor exposes others to second-hand smoke.”⁵⁵

In fact, Star apparently believes that Ariva is so unique that it adopted an entirely new descriptor for the product – a cigalett. For the purposes of opposing GSK's petition, however, Star asserts that Ariva is like many other conventional smokeless tobacco products that also purportedly do not require users to expectorate. As a result, Star argues, Ariva, like these other products, cannot also be a food product.

construction which ‘we have allowed . . . to carry the day against doubts that might exist from a reading of the bare words of a statute’’).

52 See Press Release, Star Scientific, Inc., Star Scientific and B&W Enter Into Contracts for Purchases of Starcured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products (Apr. 27, 2001) (attached as Exhibit E to GSK's Citizen Petition of Feb. 15, 2002).

53 See *id.*

54 See Star Scientific, Inc., 2001 Annual Report 12 (attached as Exhibit Q).

55 See Press Release, Star Scientific, Inc., Star Scientific Announces Test Market for Ariva Smokeless Tobacco Cigaletts; Test Markets Initiated in Dallas, Texas and Richmond, VA (Nov. 14, 2001) (attached as Exhibit I to GSK's Citizen Petition of Feb. 15, 2002).

Dockets Management Branch, FDA
October 1, 2002
Page 20 of 23

In support of this contention, Star only identifies one product by name -- "Oliver Twist Chewing Tobacco Bits®" ("Oliver Twist"). According to Star, this product is similar to Ariva because it too is "intended to dissolve in the mouth and contain[s] labels stating that expectoration is not required."⁵⁶ Putting aside the factual accuracy of that statement,⁵⁷ Oliver Twist can hardly be considered a conventional smokeless tobacco product and its existence surely cannot exempt Ariva from regulation. In fact, Oliver Twist has only been available in the United States for a short period of time and it has by no means claimed a substantial portion of the smokeless tobacco market. More importantly, to the extent that Oliver Twist is similar to Ariva, it is because Oliver Twist also possesses many of the defining characteristics of a food product. Packaged in a small rectangular container like many candy products, Oliver Twist is described by its manufacturer as a "hand-made mini-roll of tobacco treated with ingredients like strong licorice."⁵⁸ At least one retailer has suggested that Oliver Twist is very similar to chewing gum.⁵⁹ Star's case, therefore, is not advanced by a comparison to Oliver Twist.

Star's comparison of Ariva to other, more traditional smokeless tobacco products is equally unavailing. Ariva cannot be considered to be either snuff or chewing tobacco.⁶⁰ Snuff is raw powdered tobacco that is placed between the lower lip and gum.

⁵⁶ See Star Scientific's Comments Concerning Citizen Petition for Regulation of Ariva 14-15 (May 1, 2002) (Docket No. 02P-0075).

⁵⁷ The manufacturer of Oliver Twist directs users to remove the product from one's mouth after it has lost its taste. See House of Oliver Twist A/S, Presenting Oliver Twist Smokeless Tobacco, *available at* www.oliver-twist.dk (excerpts attached as Exhibit R).

⁵⁸ Based on the manufacturer's own literature describing this product, Oliver Twist Chewing Tobacco Bits may very well constitute a drug product under the FDCA since therapeutic claims are made in connection with the sale of this product. For example, the manufacturer makes the following statements about this product: "Place the portion between gum and cheek, and the nicotine is slowly released, satisfying the need for nicotine which may have been created by smoking." "If your goal is to cut down on smoking, take an Oliver Twist mini-roll every time you feel like smoking a cigarette." See House of Oliver Twist A/S, Presenting Oliver Twist Smokeless Tobacco, *available at* www.oliver-twist.dk (excerpts attached as Exhibit R). These claims are also made in connection with the sale of this product at <http://www.pipesandcigars.com/olivertwist.html> and <http://www.tinderbox.com/ounce1.htm>.

⁵⁹ "Once the long-lasting flavor is gone, the small 'pellet' is discretely removed and discarded, much like (and often mistaken for!) a piece of chewing gum." See www.tinderbox.com/ounce1.htm.

⁶⁰ GSK has previously demonstrated that the term "smokeless tobacco products" in the CSTHEA was meant to include these two types of products -- snuff and chewing tobacco. Our

Dockets Management Branch, FDA
October 1, 2002
Page 21 of 23

Chewing tobacco is raw leaf tobacco (packaged in a pouch) or plug tobacco (in brick form) that is meant to be chewed and then placed in the mouth between the cheek and the gum for up to several hours. Despite Star's claims to the contrary, both products often involve expectoration as users must clear excess saliva and tobacco which has lost its flavor. Moreover, while users of Ariva are instructed to "[p]lace a cigalatt™ piece in mouth and allow to dissolve," those using snuff and chewing tobacco (and even Oliver Twist for that matter) place the tobacco between their gum and cheek – that is, the oral cavity. Thus, Ariva differs from these products both because it is not raw, powdered or leaf tobacco – it occurs in food or candy-like form -- and it is intended to be entirely ingested. As Star's own marketing literature suggests, there is no other conventional smokeless tobacco product that possesses these characteristics.

E. Inasmuch as Internet Sales Are Not Sufficiently Controlled to Ensure that Minors do not Have Access to Tobacco Products, Candy-like Products Containing Tobacco Such as Ariva Raise Especially Significant Concerns.

Finally, in response to Star's letter of July 22, 2002, GSK believes it is necessary to set the record straight on the question of sales of Ariva over the Internet. In this context, GSK must first emphasize that it fully agrees with Star's previously stated concern that "Internet sales are not sufficiently controlled so as to ensure that minors do not have access [to tobacco products] via the Internet."⁶¹ Where GSK and Star differ, however, appears to be on the extent to which Star itself can control sales of Ariva over the Internet. While Star touts the fact that it "has monitored the sale of Ariva and has attempted to persuade Internet retailers that have chosen to sell Ariva to discontinue such sales,"⁶² GSK has demonstrated that such efforts have not prevented advertising and sale of Ariva through the Internet. Moreover, in certain instances, such websites have only stopped selling Ariva after GSK brought these problems to the attention of FDA and Star. In lieu of further engaging Star in a semantic debate on this issue, GSK believes that the facts speak for themselves:

- *April 26, 2002*: GSK advises FDA of the fact that Ariva has been sold over the Internet for at least two months through the website, tobaccobarn.com.

review of the legislative history of the Act confirms this reading of the statute. See Exhibit S (attached).

61 See Letter from Robert Pokusa, Paul, Hastings, Janofsky & Walker, LLP, to CMB, Inc. (Feb. 17, 2001) (attached as Exhibit B to GSK's Letter of June 14, 2002 Regarding Internet Sales of Ariva).

62 See Star Scientific's Letter Regarding Internet Sales of Ariva 4 (July 22, 2002) (Docket Nos. 01P-0572 and 02P-0075).

Dockets Management Branch, FDA
October 1, 2002
Page 22 of 23

GSK, through outside counsel, purchased Ariva over the Internet from this website on February 25, 2002.

- *May 1, 2002:* Star advises FDA that, prior to GSK's submission, it had requested tobaccobarn.com to discontinue sales of Ariva and that the website had done so. Star represents that it "monitors the Internet in an attempt to prevent tobacco distributors from engaging in such sales [of Ariva]."
- *May 31, 2002:* GSK, through outside counsel, undertakes a simple search of the Internet and finds that Ariva is being advertised for sale at five different websites. GSK, through counsel, purchases Ariva from two of these sites. These purchases only require submission of a credit card number and a pledge that the purchaser is 18 years or older. The products are delivered with no requirement that the recipient demonstrate proof of age.⁶³
- *June 7, 2002:* GSK, through outside counsel, purchases Ariva from a third website -- www.vafco.com. The website representative requires only a credit card number and does not ask for the purchaser's age. The product is delivered via U.S. mail with no requirement that the recipient demonstrate proof of age. The purchaser's credit card is never billed for the transaction.
- *June 14, 2002:* GSK advises FDA that, despite Star's Internet monitoring program, Ariva continues to be advertised as available for sale at five different websites operated by independent tobacco retailers and that two of these sites advertise Ariva as being "very similar in taste to an Altoid mint."
- *July 22, 2002:* Star responds to GSK's letter of June 14, 2002, by apprising FDA that, "following GSK's submission," it arranged for sales of Ariva to be discontinued at two of these sites (smokeshack.com and awesomesmokes.com) and that Ariva is not available at a third site (aldiscountcigarettes.com). Star's letter also "documented" its efforts to contact usasmokeshop.com and request immediate removal of Ariva.
- *July 22, 2002:* In its letter to FDA, Star does not report that vafco.com has also agreed to cease sales of Ariva. Rather, Star advises FDA that VAFCO protects against underage sales of tobacco products by only allowing credit card purchases and by asking purchasers to return a form that lists the

⁶³ Ariva was also ordered from aldiscountcigarettes.com, but that order was subsequently canceled because Ariva was "currently unavailable."

Dockets Management Branch, FDA

October 1, 2002

Page 23 of 23

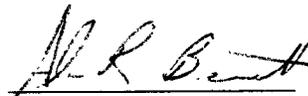
purchaser's name, address, telephone number, date of birth, and signature attesting to the veracity of age.

- *August 6, 2002*: GSK, through outside counsel, once again calls vafco.com to purchase Ariva. The VAFCO representative only asks for a credit card number and does not ask for the purchaser's age or the name on the credit card. The product arrived wrapped in a blue strip with the words "COMPLIMENTARY, NOT FOR SALE." The purchaser's credit card is never billed and, to date, he has not received a form from vafco.com that asks for information about his age.

Clearly, in light of the foregoing, FDA should not be misled into thinking that sales of Ariva through Internet sites is no longer a problem or is one that Star can alone address.

Thank you for your consideration of these comments.

Sincerely,



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Enclosures: as stated

cc: Lester Crawford, Deputy Commissioner, FDA
Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, FDA

EXHIBITS TO GSK LETTER OF OCTOBER 1, 2002

DOCKET NOS. 01P-0572 AND 02P-0075

<u>Document</u>	<u>Tab</u>
Star Scientific, Inc. Reports Second Quarter Results, Continues National Rollout of Ariva (Press Release, Aug. 15, 2002)	A
Excerpt from Discount Cigarettes Shopping Guide Newsletter, <i>available at</i> http://www.discount-cigarettes.org/may31nl.html	B
Letter from Dennis E. Baker, Associate Commissioner for Regulatory Affairs, FDA, to William B. Schultz, Zuckerman Spaeder LLP (July 1, 2002)	C
Photographs Taken By GSK Showing Placement of Ariva in Drug Stores	D
Letter from Stuart M. Pape, Counsel to Pinkerton Tobacco Company, Patton, Boggs & Blow, to John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA (Dec. 1, 1987)	E
Memorandum from Bureau of Enforcement to Directors of Bureaus and Divisions and Directors of Districts, Tobacco Products Without Therapeutic Claims (May 24, 1963)	F
Letter from Henry A. Waxman, Chairman, Subcommittee on Health and the Environment, to Frank E. Young, Commissioner, FDA (July 1, 1987)	G
Letter from Frank E. Young, Commissioner of Food and Drugs, FDA, to Henry A. Waxman, Chairman, Subcommittee on Health and the Environment (Sept. 29, 1987)	H
Federal Court Dismisses Philip Morris Lawsuit That Challenged Star Scientific Patent for Reducing Cancer-Causing Toxins (Press Release, Sept. 12, 2002)	I
Star Scientific, Inc. Comments on State Attorney Generals' FDA Submission (Press Release, July 17, 2002)	J
Star Scientific Applauds Canadian Tobacco Regulations, Virginia's "No ID, No Tobacco" Initiative; Receives BATF License for Chase City Ariva Manufacturing Facility (Press Release, July 3, 2001)	K

EXHIBITS TO GSK LETTER OF OCTOBER 1, 2002

DOCKET NOS. 01P-0572 AND 02P-0075

<u>Document</u>	<u>Tab</u>
Star Scientific Inc. Files Suit Against R.J. Reynolds to Enforce Patent For Curing Tobacco to Substantially Prevent the Formation of Cancer-causing Tobacco Specific Nitrosamines (TSNAs) (Press Release, May 24, 2001)	L
Excerpts from Star Scientific, Inc. Annual Report for 1999 (SEC Form 10-K) (Dec. 31, 1999)	M
About Star Scientific, Inc., <i>available at</i> http://www.starscientific.com	N
Excerpts from Star Scientific, Inc., Annual Report for 2001 (SEC Form 10-K) (Dec. 31, 2001)	O
Statement by Paul L. Perito to the Framework Convention on Tobacco Control of the World Health Organization (Sept. 21, 2000), <i>available at</i> http://www.starscientific.com	P
Star Scientific, Inc. 2001 Annual Report	Q
Excerpts from House of Oliver Twist A/S Description of Oliver Twist Smokeless Tobacco, <i>available at</i> http://www.oliver-twist.dk	R
Legislative History of the Comprehensive Smokeless Tobacco Health Education Act	S