

BENNETT, TURNER & COLEMAN, LLP

SUITE 750

1900 K STREET, NW

WASHINGTON, DC 20006

PHONE: (202) 833-4500

FAX: (202) 833-2859

February 15, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

CITIZEN PETITION

A. Specific Regulatory Action Requested

On behalf of **GlaxoSmithKline** Consumer Healthcare, LP ("**GSK**"), Bennett, Turner & Coleman LLP ("**BTC**") submits this citizen petition pursuant to Section 4(d) of the Administrative Procedure Act, 5 U.S.C. § 553(e); Section 402 of the Federal Food, Drug, and Cosmetic Act ("**FDCA**"), 21 U.S.C. § 342; and regulations established by the Food and Drug Administration ("**FDA**") governing citizen petitions, codified at 21 C.F.R. § 10.30. In this petition, we respectfully request FDA to notify **Star Scientific, Inc.** ("**Star**"), **Brown and Williamson Tobacco Corporation** ("**Brown & Williamson**"), and any other tobacco company planning to market a flavored candy-like product containing tobacco that it may not do so until FDA has approved a food additive petition authorizing the use of tobacco in such a product. We further request FDA to notify such companies that, should they choose to market any flavored candy-like products containing tobacco prior to approval of a food additive petition, their products will be treated as adulterated food products subject to the seizure, forfeiture, and misbranding provisions of the FDCA. See 21 U.S.C. §§ 331-334.

On December 18, 2001, the nation's major public health organizations submitted four petitions to FDA requesting the agency to regulate certain products that are currently being marketed by tobacco companies as a safer way to consume tobacco or nicotine.¹ These products

¹ These organizations are the National Center for Tobacco-Free Kids, American Cancer Society, American College of Preventive Medicine, American Heart Association, American Legacy Foundation, American Lung Association, American Medical Association, American Public Health Association, American Society of Addiction Medicine, American Society of Clinical Oncologists, American Thoracic

02P-0075

CP1 (continued...)

Dockets Management Branch

February 15, 2002

Page 2

are OMNI and Advance "low carcinogen" cigarettes, Eclipse, Nicotine Water, and Ariva™.² We fully support these petitions, and urge FDA to take the actions requested by these organizations. To that end, this petition focuses more specifically on FDA's plenary authority to regulate one of these products -- Ariva, a candy-like product containing tobacco which is manufactured by Star. In 1987, FDA took the position that another food product containing tobacco -- "Masterpiece Tobacs" -- could not be marketed in the United States until the manufacturer submitted a **food additive** petition evaluating the safety of tobacco in the **product**.³ As **described** in detail below, and as supported by the documents in the attached appendix, FDA must reach a similar conclusion about Ariva and other candy-like products containing tobacco. The agency must also take such action quickly. Star commenced test marketing of Ariva in November 2001, and it reportedly intends to market its product on a national basis imminently. Indeed, Star recently declared that Ariva will be carried in approximately 10,000 retail stores within the next 60 to 90 **days**.⁴

¹(...continued)

Society, Latino Council on Alcohol and Tobacco, National Association of Local Boards of Health, National Education Association, Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and Partnership for Prevention.

² The FDA has established the following dockets for each of these petitions: Docket No. 01P-0570 (Eclipse), Docket No. 01P-0571 (Omni and Advance), Docket No. 01P-0572 (Ariva), and Docket No. 01P-0573 (Nicotine Water).

³ The regulatory action requested in this petition would also be consistent with the recent conclusion of the Food Standards Agency of the United Kingdom that flavored candy-like products containing tobacco such as Ariva are novel food products that cannot be marketed in the European Union until they are approved by the relevant agencies. Specifically, on May 8, 2001, the Food Standards Agency advised Star that "[f]rom an initial consideration, it is the view of the Food Standards Agency that such products [Ariva and other flavored candy-like products containing tobacco] may well be classified as foods and accordingly be subject to the provisions of EC Regulation 258/97 governing novel foods and novel food ingredients." The agency went on to state that Star would need to obtain approval before its product could be sold anywhere in the European Union. **See** Letter from Nick Tomlinson, Head of Novel Foods Division, Food Standards Agency (United Kingdom), to Paul Perito, Star Scientific, Inc., of May 8, 2001 (attached as Exhibit A). Although Star subsequently wrote to the Food Standards Agency challenging that conclusion, we are not aware of any change in the position of the Food Standards Agency. **See** Letter from Paul Perito, Chairman, President and Chief Operating Officer, Star Scientific, Inc., to Nick Tomlinson, Head, Novel Foods Division, Food Standards Agency, of May 17, 2001 (attached as Exhibit B)

⁴ **See** "Star Scientific, Inc. Issues Statement on Ariva Test Marketing, Fourth Circuit Opinion," January 23, 2002, available at www.starscientific.com/frame_pages/release_frame.htm (attached as

(continued...)

Dockets Management Branch
February 15, 2002
Page 3

B. Statement of Factual and Legal Grounds

1. Factual Background: The Tobacco Industry's Efforts to Develop and Market Flavored Candy-Like Products Containing Tobacco

In April 2001, Star Scientific, Inc., announced that it intends to begin test-marketing a new tobacco product — a "cigalett™" — in parts of Texas and Virginia by the end of the summer of 2001.⁵ This product is designed to deliver nicotine through candy-like units consisting of tobacco and flavored with mint, eucalyptus, and perhaps sweeteners. Each candy-like unit will be the size of a Tic-Tac® mint, and each will contain enough tobacco (approximately 60% of the unit) to provide a dose of nicotine similar to that yielded by one cigarette. Star will market its new product under the brand name "Ariva™" in child-proof packages of twenty candy-like units with a cost comparable to a pack of cigarettes. Star has also granted an exclusive license to Brown & Williamson to sell cigaletts under its own brand name. In anticipation of marketing its cigaletts, Star has claimed that the tobacco in Ariva consists of very low levels of tobacco specific nitrosamines ("TSNAs").⁶ In this context, the company has also pointed out that "TSNAs are believed by many knowledgeable scientists and medical researchers to be among the most potent cancer-causing substances in tobacco and smoke."

Although Star has previously declared that it "supports the regulation of all tobacco-containing products by FDA," it has no intention of obtaining approval from, or apparently even consulting with, FDA prior to marketing its flavored candy-like food product containing tobacco.⁸ The same is presumably true of Brown & Williamson and any other tobacco company

⁴(...continued)
Exhibit C).

⁵ See Fairclough, Gordon, "Cigalett' Mints Target Customers Who Want Alternative to Cigarettes," *Wall Street Journal*, April 27, 2001 (attached as Exhibit D).

⁶ See "Star Scientific and B&W Enter Into Contracts for Purchases of StarCured Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless Products," April 27, 2001, available at www.starscientific.com/frame_pages/release_frame.htm (attached as Exhibit E).

⁷ See "Star Scientific, Inc. Announces New Patent for Products Containing Very Low Levels of Cancer-Causing Tobacco Specific Nitrosamines," October 24, 2000, available at www.starscientific.com/frame_pages/release_frame.htm (attached as Exhibit F).

⁸ See "New Standards for the Labeling and Marketing of Tobacco Products: Background Statement by Star Scientific Concerning the Initial Test Marketing of Advance," available at

(continued....)

Dockets Management Branch
February 15, 2002
Page 4

developing such products. In support of its position that it need not obtain approval from FDA before marketing Ariva, Star has baldly asserted that Ariva is not a food **product**.⁹ For example, in April 2001, Star's chairman, Paul L. Perito, was quoted as stating "Ariva clearly is not a food? More recently, in response to the preliminary determination of the Food Standards Agency of the United **Kingdom** that Ariva is a novel food product, Star once again adamantly claimed that Ariva is not a food product subject to the jurisdiction of national agencies responsible for food regulation." As a result, absent affirmative action by FDA, Star and other manufacturers of flavored candy-like products containing tobacco will begin marketing such products in the United States without prior review by FDA.¹²

2. The FDA Has Plenary Authority to Regulate Marketing: of Flavored Candy-Like Products Containing Tobacco Under the FDCA

Notwithstanding the tobacco industry's claims to the contrary, FDA possesses substantial authority to regulate marketing of flavored candy-like products containing tobacco under the FDCA. These products fall well within the meaning of the FDCA's term "food," which is broadly defined to include both "articles used for food or drink for man or other animals" and "articles used for components of any such article." 21 U.S.C. § 321(f). Although FDA has not delineated the particular types of products that comprise food, the relevant case law does provide

⁸(...continued)

www.starscientific.com/066745321909/newlabeling.html (attached as Exhibit G). Although Star filed and received approval of an investigational new drug application ("IND") for a tobacco gum product and thereafter commenced Phase I clinical trials, the company subsequently abandoned its efforts to undertake clinical trials of its tobacco gum product. See Star Scientific, Inc., Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (filed with the Securities and Exchange Commission) (attached as Exhibit H).

⁹ Star also has asserted that Ariva cannot be considered a drug because Star is not making smoking-cessation claims. See Fairclough, supra note 5 (attached as Exhibit D).

¹⁰ Id.

¹¹ See Letter from Paul L. Perito, supra note 3 (attached as Exhibit B) (Star stated, "ARIVA™ is neither a food nor a drug" in asserting that Ariva should not be regulated by the UK or European Union food agencies).

¹² On November 14, 2001, Star announced that it had commenced test marketing of Ariva in Dallas, Texas and Richmond, Virginia. See "Star Scientific Announces Test Market of Ariva Smokeless Tobacco Cigarettes," November 14, 2001, available at www.starscientific.com/frame_pages/release_frame.htm (attached as Exhibit I). Additional test markets will reportedly include Jackson, Mississippi and Orlando, Florida.

Dockets Management Branch
February 15, 2002
Page 5

broad, substantive meaning to the statutory term. For example, it is the “ordinary way” in which an article is used, and not any marketing claim by the manufacturer about a specific physiological purpose, that determines whether something comprises a food. See American Health Products Co., Inc. v. Hayes, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983). In addition, even if an article is not used primarily for taste, aroma, or nutritive value, it still may comprise a food. See Nutrilab, Inc. v. Schweiker, 713 F.2d 335,338 (7th Cir. 1983). Under these standards, there can be no question that flavored candy-like products containing tobacco constitute foods under the FDCA.

Indeed, in 1987, FDA concluded that another product containing tobacco -- a product that is very similar to Ariva and other flavored candy-like products containing tobacco -- is subject to the food provisions of the FDCA. That year, Pinkerton Tobacco Company (“Pinkerton”) sought to market a chewing gum product containing tobacco (“Masterpiece Tobacs”). Pinkerton asserted that its product was not a food under the FDCA because it was clearly packaged and labeled as a tobacco product. The FDA rejected that argument, however, declaring that Masterpiece Tobacs is “unlike traditional smokeless tobacco products” and it “looks, tastes, and chews like chewing gum.” The agency found it significant that, “because of the flavors and sweeteners in this gum, the saliva is likely to be swallowed as in gum chewing rather than expectorated.”¹³ Along the same lines, Ariva and similar products do not involve expectoration and they look, taste, and chew like a candy -- that is, a product that FDA regulates under the FDCA as a food.

Inasmuch as Ariva is subject to the FDCA’s requirements as a food product, FDA must conclude that the addition of tobacco to the product renders it “adulterated” under Section 402(a) of the FDCA. That section provides that “[a] food shall be deemed to be adulterated if it is, or it bears or contains any food additive which is unsafe within the meaning of Section 409” of the FDCA. 21 U.S.C. § 342(a)(2)(A). Applying this statutory test to Ariva, there can be no doubt that the tobacco in the product is a food additive for the purposes of the FDCA. The statute broadly defines the term to mean “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food” 21 U.S.C. § 321(s). To be sure, Star may argue that tobacco is not a food additive since it constitutes, at least 60% of Ariva. The courts, however, have consistently ruled that the principal component of a food can be a food additive.¹⁴

¹³ See Letter from Richard Ronk, Acting Director, Center for Food Safety and Applied Nutrition, FDA, to Stuart Pape, Patton Boggs, of September 16, 1987 (attached as Exhibit J).

¹⁴ See e.g. United States v. An Article of Food, 678 F.2d 735,738 (7th Cir. 1982) (active chemical ingredient in tablet a food additive); National Nutritional Foods Ass’n v. Kennedy, 572 F.2d 377, 389-392 (2nd Cir. 1978) (vitamin and minerals are food additives); United States v. 41 Cases, More or Less etc., 420 F.2d 1126, 113 1 (5th Cir. 1970) (principal components of chicken feed are food

(continued...)

Dockets Management Branch
February 15, 2002
Page 6

Since the tobacco in Ariva and other flavored candy-like products constitutes a food additive, such products are adulterated under the FDCA unless the manufacturer can make one of **three** showings about the use of tobacco as a food additive. First, the manufacturer must demonstrate that tobacco is generally recognized as safe ("GRAS") for use in food products by experts qualified by scientific training and experience to evaluate **its safety**. 21 U.S.C. § 321(s). Star and other companies cannot make this **showing**; tobacco is not GRAS. 21 C.F.R. Part 184, Subpart B. Alternatively, Star and other tobacco companies must show that a sanction or approval for the use of tobacco in their food products was granted prior to enactment of the food additive provisions on September 6, 1958. 21 U.S.C. § 321(s)(4). Once again, however, the tobacco companies cannot satisfy this criterion. No prior sanction for tobacco has been specified in FDA's regulations and we are not aware of **any** prior approval. 21 C.F.R. Part 181, Subpart B. Finally, Star and other companies can market these products if FDA approves a food additive petition establishing that the use of tobacco in such products is not unsafe. 21 U.S.C. § 348. No tobacco company, including Star, has filed, or apparently has any intention of filing, a food additive petition with FDA. Therefore, when marketing commences, Ariva and other **fl**avored candy-like products containing tobacco will constitute **adulterated** food products under the FDCA.¹⁵

The foregoing analysis demonstrates that FDA, must prohibit Star and other tobacco companies from marketing any flavored candy-like food products containing tobacco until the agency has approved a food additive petition addressing the safety issues raised by the tobacco in such products. 21 U.S.C. § 348(b). This is precisely the action that FDA took in the Masterpiece Tobacs case, and there is no reason that FDA cannot, or **should** not require a thorough analysis of

¹⁴(...continued)
additives).

¹⁵ Depending upon the precise contents of Ariva and similar products, FDA could reach the same conclusion under Section 402(d) of the FDCA -- the specific statutory provision governing confectioneries. 21 U.S.C. § 342(d). Since passage of the Food and Drugs Act in 1906, Congress has sought to prohibit the widespread use of "ingredients deleterious or detrimental to health" in confectioneries. To that end, Section 402(d) of the FDCA provides that a confectionery is adulterated if, among other things, it "bears or contains any nonnutritive substance" **whose use** has not been authorized by FDA through the issuance of regulations. 21 U.S.C. § 343(d)(3). As construed by FDA in a 1992 Compliance Policy Guide opinion, this provision requires any manufacturer of a confectionery to demonstrate the safety of any non-nutritive substance either by showing that the ingredient is GRAS or through submission of a petition that establishes safe conditions for **use of the** ingredient as a food additive. **See** Compliance Policy Guide 7 105 .O 1: Confectionery -- Use of Non-Nutritive Substances as Ingredients, available at www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg515-100.html. Since the tobacco in Ariva and similar products is a non-nutritive substance, these provisions would also authorize FDA to require submission of food additive petition.

Dockets Management Branch
February 15, 2002
Page 7

the safety of tobacco in flavored candy-like products as well. In fact, such action would be consistent with Star's own public statements about the importance of FDA regulating tobacco products. In Star's annual report for 1999, it advised its shareholders and the public that it has taken the "public position, unanimously supported by its Board of Directors, that it is in favor of comprehensive FDA regulation of all tobacco **products**."¹⁶ Thus, as Star itself appears to suggest, FDA must now require Star, Brown and Williamson, and any other company seeking to market a flavored candy-like product containing tobacco to submit a food additive petition before marketing of such products may **begin**.¹⁷

3. Nothing in the Case Law or Relevant Tobacco Legislation Precludes Both FDA and FTC From Jointly Regulating Flavored Candy-like **products Containing** Tobacco

In opposition to this petition, Star and other tobacco companies may assert that FDA does not have jurisdiction to regulate so-called "tobacco products" such as Ariva after the Supreme Court's 5-4 decision in FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) ("Brown & Williamson"). In fact, on December 19, 2001, **Star responded** to the petitions filed by the public health organizations by asserting that FDA does not have **authority** to regulate Ariva as a drug product after this decision.¹⁸ **Yet, Star** did not and can not respond to the public health organizations' alternative argument that FDA should regulate Ariva as a food product under the FDCA. That is because Brown & Williamson focused exclusively on FDA's authority to regulate cigarettes and smokeless tobacco products as drugs or medical devices under the FDCA. The court did not review or decide that other provisions of the FDCA, including specifically those governing food and food additives, may not be relied upon by FDA to regulate certain tobacco products. Moreover, the Brown & Williamson court repeatedly limited its conclusion about FDA's lack of jurisdiction under the FDCA to regulate tobacco products "as customarily marketed." See Brown & Williamson, 529 U.S. at 158. While the court **indicated** that the term "customarily marketed" referred to tobacco products that are sold "without manufacturer claims of therapeutic benefit," the limiting **language nonetheless** makes clear that the court was focused on traditional tobacco products. Ariva and other flavored candy-like

¹⁶ Star Scientific, Inc., Annual Report on Form 10-K for the fiscal year ended December 31, 1999, pg. 4 (filed with the Securities and Exchange Commission) (attached as Exhibit K).

¹⁷ To these ends, FDA may contact Star and Brown & Williamson at the following addresses: Star Scientific, Inc., 801 Liberty Way, Chester, VA 23836; Brown and Williamson Corporation, 200 Brown & Williamson Tower, 401 S. 4th Avenue, Louisville, KY 40202.

¹⁸ See "Statement of Paul L. Perito, Chairman, President and Chief Operating Officer, of Star Scientific, Inc., Today Issued the Following Statement," December 19, 2001 (attached as Exhibit L).

Dockets Management Branch
February 15, 2002
Page 8

products containing tobacco can hardly be considered “customarily marketed” tobacco products.¹⁹

Furthermore, even assuming that FDA regulation of Ariva and similar products were somehow subject to the Brown & Williamson decision, the Court’s decision may only preclude FDA’s exercise of authority over products containing tobacco where a direct conflict exists with legislation governing marketing of tobacco products. No such conflict exists in the instant case. We are only asking FDA to require various tobacco companies to submit a food additive petition prior to marketing of their flavored candy-like products containing tobacco. As FDA itself recognized in 1987 in the Masterpiece Tobacs case, nothing in the food additive petition process in the FDCA conflicts with the Comprehensive Smokeless Tobacco Health Education Act (“CSTHEA”), 15 U.S.C. §§ 4401- 4408 -- the principal piece of federal legislation enacted by Congress to govern smokeless tobacco products. Indeed, FDA indicated that it would be willing to exempt Pinkerton **from** any requirement under the FDCA to disclose the ingredients in Masterpiece Tobacs if such disclosure would conflict with the confidentiality provisions of the CSTHEA.²⁰ In addition, FDA has the discretion **under the** food **additive** provisions of the FDCA to allow the labeling mandated under the CSTHEA for, flavored candy-like products containing tobacco. 21 U.S.C. § 409(c)(1)(A).

At the same time, the CSTHEA does not preclude FDA from taking the action requested herein. To be sure, the statute forbids a federal agency (other than the Federal Trade Commission (“FTC”)) from requiring a warning statement relating to the use of smokeless tobacco products and health.²¹ 15 U.S.C. § 4406(a) and (b). At most, however, this provision would only bar FDA from requiring additional health statements on the packaging or in advertisements involving Ariva and similar products -- it does not prevent FDA from taking

¹⁹ Star itself calls Ariva a “flagship” product that could be used by nicotine addicts who are unable to smoke in a smoke-free environment **and** unable to use **traditional smokeless-tobacco** products because of the need to expectorate. See “Star Scientific And B&W Enter Into Contracts for Purchases Of **StarCured** Tobacco, Development and Sale of Very Low-TSNA Smoked and Smokeless **Products**,” supra note 6 (attached as Exhibit E). Thus, in Star’s own words, Ariva is unlike any other tobacco product on the market.

²⁰ The FDA also indicated that classification **of** the product as a food under the FDCA had no bearing on its status as a tobacco product under Chapter 52 of the Internal Revenue Code. See Letter from Richard Ronk, supra note 13 (attached as Exhibit J).

²¹ This provision reads in full: “No statement relating to the use of smokeless tobacco products and health, other than the statements required by section 4402 of this title, shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.”

Dockets Management Branch
February 15, 2002
Page 9

other regulatory action relating to such products. This conclusion is supported by a recent decision from the Court of Appeals of the First Circuit **construing** a substantially identical preemption provision in the CSTHEA applicable to state governments. In Philip Morris, Inc. v. Harshbarger, 122 F.3d 58, 77-78 (1st Cir. 1997), the Appeals Court concluded that the, **preemption provision in CSTHEA does not invalidate a Massachusetts law requiring tobacco product manufacturers to provide the state's Department of Public Health with an annual report listing the ingredients and nicotine yield ratings for each product sold in the state.** The preemption provision in the CSTHEA is **therefore a narrow one** that does not prevent FDA from regulating flavored candy-like products containing tobacco under the FDCA.

Accordingly, while Star **and other companies** may assert that Ariva and similar products are smokeless tobacco products subject only to the jurisdiction of the FTC under **the CSTHEA**, they cannot demonstrate that **simultaneous** regulation by FDA of such products as food products under the FDCA is impermissible. In fact, FDA and FTC have a long history of joint regulation of particular types of products. For instance, the two agencies share regulatory authority governing over-the-counter drug promotion pursuant to a 1971 Memorandum of Understanding.²² More recently, **the** FTC and FDA have cooperated extensively in regulating **the** promotion and **marketing** of dietary supplements, particularly on issues involving health claims **made** for these increasingly popular products.²³ And, of course, FDA itself has a long history of jointly regulating certain products that satisfy two different statutory definitions under the FDCA.²⁴ Consequently, while the tobacco industry may claim that flavored candy-like products containing tobacco are smokeless tobacco products, that does not mean that such products are not also food products subject to the concurrent jurisdiction of FDA.

4. If Ariva and Similar Products Can Not be Regulated by Both the FDA and FTC, then FDA Must Exercise Unilateral Jurisdiction Over Such Products under the FDCA

Assuming arguendo that for **some reason** FDA and the FTC cannot exercise joint jurisdiction over flavored candy-like products containing **tobacco**, **FDA should then be** the agency that exercises authority over such products. While Ariva and similar products fall

²² See "Relations with Other Agencies: Working Agreement between the FTC and the Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 985 1 (Sept. 9, 1971).

²³ See "Dietary Supplements: An Advertising Guide for Industry," FTC Guidance Document, at www.ftc.gov.

²⁴ For example, "cosmeceuticals" are regulated by FDA both as cosmetics and pharmaceuticals because they make medicinal or drug claims. See "Cosmeceutical" Talk Paper, FDA Website, at www.vm.cfsan.fda.gov/~dms/.

Dockets Management Branch
February 15, 2002
Page 10

squarely within FDA's jurisdiction under the FDCA, the same cannot necessarily be said of the FTC. Under the CSTHEA, the term smokeless tobacco is defined as "any finely cut, ground, powdered, or leaftobacco that is intended to be placed in the oral cavity." 15 U.S.C. § 4408(1). Ariva and other flavored candy-like products containing tobacco fall outside the scope of this definition in at least two ways. First, the statute contemplates that smokeless tobacco is the raw tobacco itself -- not tobacco powder that is encapsulated within, or hardened into, a candy-like product resembling a mint. Second, the definition is limited, to those tobacco products that are "intended to be placed in the oral cavity." Ariva and similar products, on the other hand, are intended to be ingested by consumers -- not just placed in the oral cavity and expectorated."

Finally, this interpretation of the CSTHEA is further supported by amendments to the Internal Revenue Code that Congress adopted at approximately the same time that it enacted the CSTHEA. Pub. L. No. 99-272, 100 Stat. 312. Chapter 52 of the Code imposes federal excise taxes on tobacco products and sets forth permitting requirements governing businesses engaged in the manufacture and importation of tobacco products. 26 U.S.C. § 5701 et. seq. The Bureau of Alcohol, Tobacco and Firearms ("ATF") is charged with enforcing these provisions. When CSTHEA was enacted, Congress extended these provisions of the Code to smokeless tobacco products. In doing so, Congress (and subsequently the ATF) narrowly defined the term "smokeless tobacco product" to mean "any snuff or chewing tobacco." 26 U.S.C. § 5702(n); 27 C.F.R. § 270.11. "Snuff" was, in turn, defined to mean "any finely cut, ground, or powdered tobacco that is not intended to be smoked." *Id.* "Chewing tobacco" was defined as "any leaf tobacco that is not intended to be smoked." *Id.* These amendments, thus reflect Congressional concern with only two types of smokeless tobacco products, and Ariva and other candy-like products containing tobacco do not fit into either category.

C. Environmental Impact

The action requested is subject to a categorical exclusion from environmental assessment under 21 U.S.C. § 25.30(h).

²⁵ The legislative history surrounding CSTHEA lends further support to the proposition that Congress was principally concerned about the human health hazards posed by traditional smokeless tobacco products. The Senate Report accompanying CSTHEA, for example, consistently refers to smokeless tobacco products as "chewing tobacco and snuff" *See* Sen. Rep. No. 99-209 at 3 (1986), *reprinted in* 1986 U.S.C.A.N. 7. Key sponsors of this legislation also referred to smokeless tobacco products in this manner. *See e.g.*, Statement of Representative Collins ("[e]ducation is the key ingredient in the formula for, making sure that all users are, well-informed of the risks that they are taking in chewing tobacco and dipping snuff.") 132 Cong. Rec. E199 (Feb. 4, 1986); and Statement of Representative Richardson ("smokeless tobacco products include snuff and chewing tobacco.") 132 Cong. Rec. H245 (Feb. 3, 1986).

Dockets Management Branch
February 15, 2002
Page 11

D. Economic Impact

Pursuant to 21 C.F.R. §10.30(b), we will provide data concerning the economic impact of the action requested should such information be requested by FDA.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



Alan R. Bennett
Bruce S. **Manheim**, Jr.
Bennett, Turner & Coleman, LLP
1900 K Street, N.W., Suite 750
Washington, D.C. 20006
(202) 833-4500

Attorneys for **GlaxoSmithKline** Consumer
Healthcare, LP

cc: Dr. Bernard Schwetz, Acting Commissioner, FDA
Mr. Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, FDA