

Citizen Petition

This is one of four petitions submitted today to the Food and Drug Administration (“FDA”) by the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventive Medicine, the American Heart Association, the American Legacy Foundation, the American Lung Association, the American Medical Association, the American Public Health Association, the American Society of Addiction Medicine, the American Society of Clinical Oncologists, the American Thoracic Society, the Latino Council on Alcohol and Tobacco, the National Association of Local Boards of Health, the National Education Association, the Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and the Partnership for Prevention. The other petitions concern: Ariva tobacco lozenges, OMNI and Advance “low carcinogen” cigarettes, Eclipse and Nicotine Water. Each petition urges FDA to regulate a product that is being marketed to users of traditional tobacco products as a safer, healthier way of consuming tobacco or nicotine, or both.

Although the Supreme Court held last year that the FDA does not have jurisdiction over traditional tobacco products as customarily marketed, the Court left undisturbed the agency’s jurisdiction over (1) nicotine-containing products other than traditional tobacco products, and (2) traditional tobacco products that make drug claims. Yet the manufacturers of Ariva mint-flavored nicotine lozenges, which are packaged more like a smoking cessation medication and taste more like candy and will be used more like candy than a traditional tobacco product, are marketing this product without first submitting it to FDA for approval, and in fact without going through any government review. Instead, the manufacturer claims the product is exempt from government oversight just because it contains tobacco. As we demonstrate in this petition, these

lozenges are in fact subject to various requirements of the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, as traditionally interpreted by the agency and the courts. Therefore, the FDA should grant this petition and prohibit the sale of the product until the manufacturer has complied with the law.

Ariva

According to news reports and company press releases, Star Scientific, Inc. (“Star”) has recently begun to test market “Ariva,” a mint-flavored lozenge containing tobacco. The lozenge is the size of a Tic-Tac mint, 60% of which is compressed powdered tobacco. Star represents that the remainder of the product consists of mint and eucalyptus flavoring.¹ Star calls Ariva a “cigalett,” and claims it is designed for situations – in the workplace or on an airplane, for example – when people cannot smoke, or do not want the “unpleasant aesthetics” of smokeless tobacco products. Ariva is also called a “lozenge” and is designed to be used like one -- placed in the mouth and ultimately ingested.

A. Action Requested

Petitioners request that FDA classify, and therefore regulate, tobacco lozenges as “drugs” within the meaning of the FFDCA. In the alternative, we request that FDA classify and regulate the lozenges as “foods” containing an unapproved food additive under the FFDCA.

¹ Larry O’Dell, “Company Plans Nicotine Lozenges,” *AP Online*, April 27, 2001; Gordon Fairclough, “‘Cigalett’ Mints Target Customers Who Want Alternative to Cigarettes,” *Wall St. J.*, April 27, 2001; 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,” *available at* http://www.starscientific.com/main_pages/release042701.html (April 27, 2001) (hereinafter “StarCured Tobacco Press Release”) (Attachment A).

B. Statement of Grounds

According to Star's press release about Ariva, the lozenge 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."² Star has touted the product's possible health-related advantages, noting it will contain "StarCured tobacco," which, according to Star, contains "less cancer-causing toxins (TSNAs) than conventional products."³ Despite this vigorous promotion, the final packaging does not contain health claims, nor does it mention that it contains lower levels of nitrosamines.

When companies have previously attempted to market nicotine-containing tobacco products in any form other than conventional cigarettes, pipe tobacco, cigars, or traditional forms of snuff and chewing tobacco, FDA has consistently determined that these products must be regulated under the FFDCFA. Indeed, FDA has never officially permitted the marketing of unconventional, nicotine-containing tobacco products. For purposes of the applicability of the FFDCFA, there is no difference between Ariva and nicotine replacement products (such as nicotine gum), or products like Masterpiece Tobacs or Gumsmoke, that the agency has previously decided to regulate. Like nicotine replacement gum, Ariva will be marketed as a source of nicotine for people to use to address symptoms of nicotine addiction, and, despite the presence of tobacco, it will be sold in food form. Tobacco lozenges therefore fall squarely within FDA's regulatory authority under the FFDCFA.

² "StarCured Tobacco Press Release," *supra* n.1 (Attachment A).

³ *Id.* "TSNA" stands for "tobacco-specific nitrosamine," a confirmed carcinogen.

As we demonstrate in Section 1 below, FDA should, consistent with its regulation of nicotine replacement gum and similar products, classify and regulate Ariva tobacco lozenges as “drugs” under the FFDCFA. In the alternative, as we demonstrate in Section 2, FDA should regulate Ariva as a food. In Section 3, we explain that the Supreme Court’s recent decision in *FDA v. Brown & Williamson*, 529 U.S. 120 (2000), did not affect longstanding FDA authority to regulate Ariva and similar products.

1. Tobacco lozenges are “drugs” for purposes of the FFDCFA.

The FFDCFA defines “drug” to include “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body.” 21 U.S.C. §§ 321(g)(1)(B), 321(g)(1)(C). As set forth below, the lozenge, like other nicotine-substitution products, is intended to deliver nicotine to the user to mitigate, or temporarily to treat, nicotine addiction. In addition, because it is a nicotine source, the lozenge is intended to affect the structure or function of the body. Finally, Star has made claims about the potential health benefits of using the product that FDA has previously said constitute “drug claims,” and, therefore, the product should be regulated as a drug.

a. “Ariva” lozenges are intended temporarily to treat or to mitigate the disease of nicotine addiction.

It is widely recognized that nicotine addiction is a disease.⁴ FDA has approved several products, including the nicotine patch, nicotine gum, and the nicotine inhaler, as drug treatments

⁴ World Health Organization, 3 *International Statistical Classification of Diseases and Related Health Problems* 537 (10th rev. 1994); American Psychiatric Ass’n, *DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders* 264-65 (4th ed., text rev. 2000); see also Office on Smoking and Health, Department of Health and Human Services, “The Health Consequences of Smoking: Nicotine Addiction, a Report of the Surgeon General” (1988) (hereinafter “Surgeon General’s Report”), available at http://www.cdc.gov/tobacco/sgr_1988.htm.

for nicotine addiction. Those products deliver nicotine to people who are addicted to that drug, but who do not want to smoke cigarettes or use smokeless tobacco products.⁵

Star's own statements about Ariva confirm that the product is intended for those who are addicted to nicotine. As the company explains, the lozenge

has been developed to meet the needs of adult smokers when they are in smoke-free environments. . . [It] is also directed to conventional smokeless product users who want the option of choosing a smokeless tobacco product . . . while avoiding the need to expectorate. . . . [Ariva] can provide this alternative in the workplace, during travel, and in other environments.⁶

A spokesperson for Star has further acknowledged that the prospective market for Ariva consists of tobacco addicts, and has said, "like it or not . . . there are millions of people who cannot, or will not, stop smoking."⁷ On its web site, Star highlights nicotine addiction in its explanation of the reasons it believes there is a market for products like Ariva:

"Cessation" ought to be the first consideration of any long-term smoker. . . . Yet, since we recognize that it is highly unlikely for a range of reasons, including nicotine addiction, that a significant portion of the 1.2 billion people who smoke each day will quit in the near future, there is a compelling need for tobacco product modification.⁸

⁵ See, e.g., *The Science of NRT (Nicotine Replacement Therapy)*, at http://www.nicorette.com/nicr_internal/nrt4.html (last visited December 16, 2001) (Attachment B).

⁶ "StarCured Tobacco Press Release," *supra* n.1 (Attachment A); see also Paul L. Perito, Chairman, President, and CEO, Star Scientific, Inc., Letter to the Editor, *Sarasota Herald-Trib.*, June 1, 2001, at A10.

⁷ William Hathaway, "Cigaretts: A 'Safer' Nicotine?," *Hartford Courant*, May 21, 2001, at A1.

⁸ *New Standards for the Labeling and Marketing of Tobacco Products: Background Statement by Star Scientific, Inc. Concerning the Initial Test Marketing of Advance (in Virginia and Kentucky)*, at <http://www.starscientific.com/066745321909/newlabeling.html> (last visited December 16, 2001) (hereinafter "Background Statement by Star") (Attachment C).

It is clear, then, that the makers of Ariva anticipate that many people who will buy its product are people who are addicted to nicotine. The product exists to give those people an alternative source of nicotine at times when they cannot, or do not want to, use conventional tobacco products. The purpose of the product is to allow someone who is addicted to nicotine to avoid withdrawal symptoms. Ariva is therefore functionally analogous to nicotine-substitution products, like nicotine gum, that were created to serve the same purpose and are regulated by the FDA as drugs. The only apparent difference is that other nicotine-substitution products are intended as, and marketed as, permanent solutions to nicotine addiction (“cessation aids”), while Star plans to market Ariva as a temporary, situation-specific treatment. The distinction is irrelevant to a determination of whether Ariva lozenges are intended for use in treatment *or mitigation* of a disease under the FFDCA. Cough syrup, for example, is a temporary treatment of the symptoms of a disease, but is no less a drug because it is not intended as a permanent cure. Ariva was developed for the same disease as nicotine-substitution products, to achieve an analogous effect, and should be regulated as a drug.

Star has studiously avoided comparisons to other nicotine-substitution products, asserting its product is not a drug.⁹ That Star chooses to call the lozenge a “tobacco product,”¹⁰ however,

⁹ See William Hathaway, “Cigaretts: A ‘Safer’ Nicotine?,” *supra* n. 7 (“Machir [spokesperson for Star] stresses the company makes no health claims for its product. . . . The makers [of Ariva] also make no claim that it will help people quit smoking. If they did, Ariva would come under the same oversight as nicotine gum and patches.”).

¹⁰ See “StarCured Tobacco Press Release,” *supra* n.1 (Attachment A); Gordon Fairclough, “Cigarette Mints Target Customers Who Want Alternative to Cigarettes,” *supra* n.1 (“Star, which has called for FDA regulation of tobacco, argues that Ariva is exempt from the agency’s jurisdiction under current law because it is a tobacco product”); Larry O’Dell, “Company Plans Nicotine Lozenges,” *supra* n. 1.

does not end the inquiry.¹¹ Analysis of “intended use” under the FFDCA is not limited to the manufacturer’s explicit statements or marketing strategy. FDA may ascertain actual intent on the basis of relevant objective evidence as well.¹² As the regulations implementing the FFDCA provide, “The intent . . . may be shown by the circumstances surrounding the distribution of the article . . . It may [also] be shown by the circumstances that the article is . . . being offered and used for a purpose for which it is neither labeled nor advertised.” 21 C.F.R. § 201.128.¹³

FDA has concluded that a manufacturer’s intent under the FFDCA can be inferred when a reasonable person in the position of the manufacturer would foresee that the product will be used in a certain way (to treat or mitigate a disease) or will have certain effects (in this case, pharmacologic effects on the structure or function of the body).¹⁴ That Ariva will be used by consumers as a temporary treatment for, or to mitigate, nicotine addiction is clear. It is not only foreseeable to Star; it is evident in the company’s own statements about the product. Though

¹¹ Indeed, the FDA has properly asserted jurisdiction over tobacco products themselves when the manufacturers made drug claims about the products. *U.S. v. 46 Cartons*, 113 F. Supp. 336 (D. N.J. 1953); *U.S. v. 354 Bulk Cartons*, 178 F. Supp. 847 (D. N.J. 1959). FDA jurisdiction over tobacco products where the manufacturer makes “drug claims” was not disturbed by the U.S. Supreme Court’s recent decision in *FDA v. Brown & Williamson*, 529 U.S. 120, 150. See pp. 16-18, *infra*.

¹² *National Nutritional Foods Ass’n v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977).

¹³ Courts have held that evidence of consumer use is relevant in determining a product’s “intended use.” *National Nutritional Foods Ass’n v. Mathews*, 557 F.2d at 334 (FDA may determine intent from relevant objective evidence, including consumer use); *Action on Smoking & Health v. Harris*, 655 F.2d 236, 239-240 (D.C. Cir. 1980) (consumer use can be relevant in determining manufacturer intent).

¹⁴ Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (Final Rule), 61 Fed. Reg. 44,396, 44,690 (Aug. 28, 1996). Although that regulation is no longer in effect since the Supreme Court’s decision in *Brown & Williamson*, the Court did not address FDA’s analysis of “intended use” under the FFDCA. 529 U.S. at 131-32.

Star has so far failed to advertise Ariva as a treatment for nicotine addiction similar to other nicotine substitution products (and, according to press reports, will not), it is clear Ariva is “intended” to treat or mitigate a disease for purposes of the FFDCA.

Further, and perhaps more significantly, whether or not Star chooses to advertise it as such, it bears repeating that the lozenge is functionally similar to products like nicotine gum. If, for example, a manufacturer of nicotine gum decided to use ground tobacco in its product as the nicotine source, that product would be no less a “drug” for purposes of the FFDCA. According to one news article, “the advent of Ariva and similar products marks a significant step toward the emergence of a market not for tobacco but for nicotine.”¹⁵ Failing to regulate Ariva lozenges as other nicotine-substitution products are regulated would allow tobacco companies to sell an equivalent product without any requirement that the product be found safe and effective by the FDA.

b. Ariva lozenges are intended to affect the structure or a function of the body.

Even if Ariva lozenges were not intended to treat nicotine addiction, they would fall within the FFDCA’s definition of “drug” because they are “intended to affect the structure or any function of the body of man.” 21 U.S.C. § 321(g)(1)(C).

A 1988 Surgeon General’s report documented the precise effects of nicotine on the body.¹⁶ Stated generally, nicotine’s actions on the structure and functions of the body include “electrocortical activation, skeletal muscle relaxation, and cardiovascular and endocrine

¹⁵ Gordon Fairclough, “‘Cigalett’ Mints Target Customers Who Want Alternative to Cigarettes,” *supra* n.1.

¹⁶ “Surgeon General’s Report,” *supra* n.4, at 75-144.

effects.”¹⁷ Nicotine also acts upon receptors in nerve cells to create both nicotine tolerance and nicotine dependence.¹⁸ It is clear, then, that Ariva tobacco lozenges “affect the structure or function of the body.”

As explained above, the great majority of users of tobacco products, the prospective market for Ariva lozenges, are addicted to nicotine.¹⁹ It is well documented that nicotine users, even if not addicted, seek the drug for its pharmacological effects, including relaxation, stimulation, and weight control.²⁰ A study of nicotine nasal spray showed how these effects, rather than any sensory effect associated with the products that contain nicotine, motivate people to consume the drug. In that study, users of nicotine nasal spray showed characteristics of addiction, despite the unpleasant experience of using the spray itself, which has a highly unpleasant taste if allowed to run down the nasal passages into the throat, and irritates the nasal passages themselves, even causing ulcers in the nasal mucosa if overused.²¹

Consumers will use Ariva as a source of nicotine, a substance they seek precisely because of its effects on the structure or function of the body. As is set out more fully in pages 5-9

¹⁷ *Id.* at 14.

¹⁸ Kolawole S. Okuyemi, Jasjit S. Ahluwalia, and Kari J. Harris, “Pharmacotherapy of Smoking Cessation,” 9 *Archives Fam. Med.* 270, 271 (2000) (Attachment D). More specifically, nicotine binds to “nicotinic acetylcholine receptors” in the nervous system, producing “enhanced alertness and mild euphoria.” It also increases the number of these receptors, creating a need for more nicotine to maintain mood. *Id.*

¹⁹ 75-90% of frequent smokers and over one-third of smokeless tobacco users are addicted to nicotine. Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents (Proposed Rule), 60 *Fed. Reg.* 41,314, 41487 (Aug. 11, 1995) (synthesizing data on nicotine addiction).

²⁰ *See generally* “Surgeon General’s Report,” *supra* n. 4.

²¹ 60 *Fed. Reg.* at 41,565 (citing FDA Drug Abuse Advisory Committee Background Information, Joint Abuse Liability Review of Nicotine Nasal Spray (Aug. 1, 1994)).

above, Star's own materials make clear the company intends that result. Ariva should therefore be regulated as a drug under the FFDCA.

c. Star has made “drug” claims about potential health benefits of the specially cured tobacco in Ariva.

Prior to marketing Ariva, Star, which characterizes itself as “a technology-oriented tobacco company with a health-related corporate mission,”²² repeatedly advertised that the tobacco in Ariva – cured using Star’s “StarCure” technology – contains far lower levels of carcinogens (TSNAs) than are found in conventionally cured tobacco.²³ The company also said Ariva packages will bear the warning, “There is no safe tobacco product,”²⁴ and that it does not intend to make health claims about the product, but its premarket promotion so far belies that contention. In a letter to the editor of a newspaper, Paul Perito, President and CEO of Star wrote:

Ariva is an outgrowth of our success in developing a tobacco-curing technology (StarCured) that prevents the formation of one of the most potent and abundant carcinogens in tobacco leaf and smoke – tobacco-specific nitrosamines (TSNAs). . . . Each cigarett is manufactured using very low-TSNA, StarCured tobacco.²⁵

Star has also claimed support from the public health community for products like Ariva:

[H]ighly respected independent scientific and public health consultants . . . urged Star to accelerate the development of non-combustible tobacco products so as to provide adult tobacco users

²² “Background Statement by Star,” *supra* n. 8 (Attachment C).

²³ Larry O’Dell, “Company Plans Nicotine Lozenges,” *supra* n.1; “StarCured Tobacco Press Release,” *supra* n.1 (Attachment A).

²⁴ Larry O’Dell, “Company Plans Nicotine Lozenges,” *supra* n.1.

²⁵ Paul L. Perito, Letter to the Editor, *supra* n.6.

. . . choices that significantly reduce exposure to the cancer-causing toxins that are delivered in all conventional cigarette products (TSNAs).²⁶

In 1997, Star proposed to sell a chewing gum called “GumSmoke,” making claims about the safety of the product that were similar to claims Star has made about Ariva.²⁷ Star planned to market GumSmoke in much the same way it earlier promoted Ariva lozenges: “gum for smokers,” “when you can’t smoke,” “the smoke that has no match,” and “the alternative you need.” Star also issued a press release that suggested that GumSmoke would contain specially processed tobacco that was “TSNA-free.”²⁸ FDA objected, concluding that Star’s presentation of GumSmoke could create the perception that it was a “milder, safer form of smokeless tobacco, or a milder, safer substitute for smoking conventional cigarettes.”²⁹ FDA ruled that such claims would constitute “drug claims” and would cause the product to be regulated as a drug.

Addressing Star’s presentation of “GumSmoke” as a safer (smokeless and TSNA-free) alternative to traditional tobacco products, FDA explained that representations that use of a given product “may prevent or mitigate diseases associated with tobacco use” will be “regarded by the agency as ‘drug’ claims under section 201(g)(1) of the [FFDCA]” and will “cause the product to be a ‘new drug’ within the meaning of section 201(p) of the Act.”³⁰ Star’s original promotion of Ariva contains the very same claims, suggesting that the lozenges are a safer alternative to

²⁶ “StarCured Tobacco Press Release,” *supra* n.1 (Attachment A).

²⁷ Letter from Kevin Budich, Compliance Officer, Center for Drug Evaluation and Research, FDA, to Paul L. Perito, then-outside counsel for Star Scientific (July 22, 1998) (Attachment E).

²⁸ *Id.*

²⁹ *Id.*

³⁰ Letter from Kevin Budich to Paul Perito, *supra* n. 27 (Attachment E).

traditional tobacco products that will both temporarily treat nicotine addiction and allow the user to avoid cancer-causing nitrosamines.

We understand that Star represents that at the present time it will not make explicit health claims in connection with marketing Ariva. Since, as we have explained elsewhere in this petition, the FDA has ample authority to regulate Ariva even if Star is not making health claims, we do not argue that the FDA must at this time decide whether the health claim statements that Star has previously made for Ariva would be a sufficient basis for FDA to assert jurisdiction over Ariva. However, should FDA reject the other bases of jurisdiction, then petitioners urge the agency to investigate the health claims Star has previously made, and any other statements made by Star, to determine whether those statements are a sufficient basis for asserting jurisdiction, just as it did for Gumsmoke.

2. Under the FFDCA, Ariva lozenges are “foods” containing a “food additive”.

Even if tobacco lozenges were not drugs, they are “foods”³¹ containing tobacco as a “food additive”³² under the FFDCA. What makes Ariva distinct from traditional smokeless tobacco products and more like a food is its very form – that of a hard candy or lozenge. They will be used as mint tasting candy (or “confections”) containing tobacco. FDA has already conducted an analysis of a similar product, “Masterpiece Tobacs,” and determined it is a food under the FFDCA.³³ Masterpiece Tobacs was a gum that contained tobacco. Like Ariva, the

³¹ Though, as outlined above, Ariva would most appropriately be regulated as a drug, the definitions of “food” and “drug” are not mutually exclusive under the FFDCA. Products may be foods but still be used, and regulated, as drugs. *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983).

³² 21 U.S.C. § 321(s).

³³ Letter from Richard J. Ronk, Acting Director, Center for Food Safety and Applied Nutrition, Department of Health and Human Services, to Stuart Pape, attorney for Pinkerton Tobacco Co.

manufacturer argued that it was a “tobacco product,” and the manufacturer argued it should be regulated as smokeless tobacco. Analyzing the form of the product and the way it was to be used, FDA concluded it was gum -- made like gum and designed to be used like gum -- but with an added ingredient. The analysis of Ariva should be no different, no matter how much tobacco it contains, given its form and how it will be used.

As described above, Ariva is a hard mint- and eucalyptus-flavored lozenge, comparable to a Tic-tac mint, 60% of which is powdered tobacco.³⁴ Star carefully refers to its product as a “tobacco lozenge” or a “compressed tobacco pellet,” no doubt to avoid its being regulated as a food.³⁵ One of its spokespeople pleaded with a reporter writing about Ariva: “Please, please don’t call it a candy. It’s 60% pressed tobacco.”³⁶

As is evident in the above-quoted exhortation of one of its spokespeople, Star is no doubt concerned that a mint the size of a Tic-Tac might be considered a candy. It has even announced it will package Ariva in childproof packaging -- an acknowledgment that, like candy, it is

(Sept. 16, 1987) (Attachment F); Letter from John M. Taylor, Associate Commissioner for Regulatory Affairs, Department of Health and Human Services, to Stuart Pape, attorney for Pinkerton Tobacco Co. (Apr. 12, 1988) (Attachment G).

³⁴ Even an ingredient that is the “principal ingredient” of a product can be a “food additive” for purposes of the FFDCFA, as long as it is not the only active ingredient. *U.S. v. Two Plastic Drums*, 984 F.2d 814, 819-820 (7th Cir. 1993) (citing *U.S. v. An Article of Food*, 678 F.2d 735, 738 (7th Cir. 1982)); *U.S. v. 29 Cartons * * * an Article of Food*, 987 F.2d 33, 37-38 (1st Cir. 1993).

³⁵ See Larry O’Dell, “Company Plans Nicotine Lozenges,” *supra* n. 1 (“Ariva is a tobacco product, not a food product, and therefore is not subject to federal Food and Drug Administration regulation, Star Scientific says.”).

³⁶ William Hathaway, “Cigarettes: A ‘Safer’ Nicotine?,” *supra* n. 1, quoting Sara Troy Machir, spokesperson for Star Scientific. See also Paul L. Perito, Letter to the Editor, *supra* n. 6 (“It is not a mint or a candy – it is compressed tobacco.”).

potentially attractive to children.³⁷ Moreover, Star’s concern is well founded. Ariva can be considered “confectionery” – it is a hard, mint-flavored pellet, called a “lozenge,” compared most closely with a Tic-tac, designed to be consumed the way candy is. There is a serious concern that it will be attractive to children despite its packaging. Under the FFDCA, “confectionery” is food – with or without additives.³⁸

Star may argue that Ariva should be considered a smokeless tobacco product – Star’s promotional materials about Ariva call the lozenges “smokeless hard tobacco products.”³⁹ As FDA said when presented with Masterpiece Tobacs gum, however, that a manufacturer calls an item a “tobacco product” and labels it as such does not mean it is not a food.⁴⁰ Because Masterpiece Tobacs “look[ed], taste[d], and chew[ed] like chewing gum” and contained sweeteners that made it likely the saliva would be swallowed, as it is with chewing gum (but as it

³⁷ Its potential attractiveness to children led the government of New Zealand to issue a nationwide customs alert for the product. Importers can be prosecuted for attempting to bring Ariva into the country. “Customs Issues Warnings Over Nicotine Sweet,” *The Dominion (New Zealand)*, June 19, 2001, available at 2001 WL 21958564.

³⁸ 21 U.S.C. 342 (d) (explaining when “confectionery containing alcohol or nonnutritive substance[s]” qualifies as an adulterated food); 21 C.F.R. §1.24 (explaining the circumstances under which confectionery need not bear complete food labeling information).

³⁹ “StarCured Tobacco Press Release,” *supra* n.1 (Attachment A).

⁴⁰ Letter from Richard J. Ronk, Acting Director, Center for Food Safety and Applied Nutrition, Department of Health and Human Services, to Stuart Pape, attorney for Pinkerton Tobacco Co., *supra* n. 33 (Attachment F). Further, that Ariva will have a different effect – that of providing its consumer with nicotine – does not alter its status as a food. “Foods” need not necessarily be articles used solely for taste, aroma or nutritive value. *Nutrilab v. Schweiker*, 713 F.2d at 338. That Ariva functions as a nicotine source, however, shows Ariva would be most appropriately regulated as a drug, as explained above.

is not with traditional smokeless tobacco products), FDA reasoned, Masterpiece Tobacs was a gum, and was a food for purposes of the FFDCFA.⁴¹

The same is true of Ariva. That the lozenges will contain tobacco – even if it contains more than 50% tobacco – does not exempt them from the definition of “food” under the FFDCFA any more than was the case with Masterpiece Tobacs. Similarly, that the user may seek Ariva for its nicotine and will “be able to discern it contains tobacco”⁴² by its taste makes it no less a food, containing an unapproved food additive (tobacco).

No matter how much tobacco Ariva contains, Ariva lozenges present the same situation and require the same analysis as Masterpiece Tobacs. The lozenges – hard pellets with mint and eucalyptus flavoring, comparable to Tic-Tacs – will take the form of a mint, will be flavored like a mint, and are designed to be used like a mint. As was true of Masterpiece Tobacs, Ariva does not take the form of a traditional smokeless tobacco product; indeed, in the case of Ariva, that is one of its main selling points. Consumers of Ariva will not have to expectorate when using the product, but will instead ingest their saliva, making Ariva a food, and not a traditional smokeless tobacco product. As FDA concluded in Masterpiece Tobacs, when a product is sold “in food form,” as Ariva is, it is appropriately regulable as a food under the FFDCFA.⁴³ Ariva should be

⁴¹ *Id.*

⁴² Larry O’Dell, *Company Plans Nicotine Lozenges*, *supra* n.1 (quoting Sara T. Machir, spokesperson for Star Scientific: “The prototype product has mint flavoring, but the user will be able to discern it’s a tobacco product”).

⁴³ Letter from John M. Taylor, *supra* n. 33 (Attachment G) (citing *U.S. v. Technical Egg Products, Inc.*, 171 F. Supp. 326, 328 (N.D. Ga. 1959), for the proposition that items are foods when sold in the form of foods, regardless of their intended use).

considered an adulterated food because it contains a food additive (tobacco) that is not generally recognized as safe for use in foods.⁴⁴

3. The Supreme Court in *Brown & Williamson* preserved FDA's authority to regulate products like Ariva.

In its recent decision in *FDA v. Brown & Williamson*, 529 U.S. 120 (2000), the U.S. Supreme Court held that FDA does not have jurisdiction to regulate conventional tobacco products as customarily marketed. In that case, the Court invalidated an FDA regulation asserting jurisdiction over conventional cigarettes and smokeless tobacco products, finding that Congress had not granted FDA authority over traditional tobacco products as customarily marketed. Among the reasons cited by the Court for the conclusion that Congress had not intended to grant FDA authority over traditional tobacco products was that Congress had enacted legislation concerning tobacco inconsistent with the Court's view that if FDA asserted jurisdiction over traditional tobacco products, the agency would be required to ban the sale of those products. 529 U.S. at 137. The Court clearly concluded that Congress had not intended to ban traditional tobacco products as customarily marketed even if they were dangerous. The exemption carved out for traditional tobacco products as customarily marketed does not, however, apply more broadly. For the reasons discussed below, that decision does not preclude FDA jurisdiction over Ariva lozenges.

First, the entire focus of the Court's opinion was the FDA's 1996 jurisdictional statement and regulation reversing its longstanding position that it should not regulate traditional cigarettes and smokeless tobacco products.⁴⁵ Conversely, the decision did *not* disturb FDA's longstanding

⁴⁴ See Letter from Richard J. Ronk, *supra* n. 33 (Attachment F).

⁴⁵ 529 U.S. at 125 (citing 61 Fed. Reg. 44,619 - 45,318).

interpretation of its authority to regulate tobacco products as drugs and foods in circumstances that do not involve traditional tobacco products as customarily marketed. As explained above, Ariva bears no resemblance to traditional tobacco products as customarily marketed, namely cigarettes, cigars, pipe tobacco, and conventional forms of chewing tobacco and snuff. It is instead virtually indistinguishable from products the FDA regulates, like nicotine gum, and some products the FDA has indicated it would not permit to be marketed, like Masterpiece Tobacs, or tobacco products bearing drug claims. As such, FDA's precedents demonstrate that the agency had the authority to regulate Ariva before 1996. Therefore, under *Brown & Williamson*, FDA continues to have that authority today.

Second, the Court's holding does not disturb FDA's authority to regulate tobacco products when those products bear drug claims. As it framed the precise issue before it, the Court explained: "We granted the government's petition for certiorari to determine whether the FDA has authority to regulate tobacco products *as customarily marketed*." 529 U.S. at 133 (emphasis added) (citation omitted). The qualifying phrase, "as customarily marketed," reflects the Court's acknowledgement of an exception "well-established" in prior case law for cigarettes and other traditional tobacco products where the manufacturer has made a drug claim about the product. 529 U.S. at 158. The Court found that Congress had effectively ratified FDA's prior interpretation of its own authority, 529 U.S. at 158-59, which historically included, and continues to include, FDA regulation of tobacco products bearing drug claims.⁴⁶ Thus, FDA retains authority to regulate tobacco products – even cigarettes and smokeless tobacco products – when those products bear drug claims. As outlined above, early on in its promotion of Ariva, Star

⁴⁶ See *U.S. v. 46 Cartons*, 113 F. Supp. 336 (D. N.J. 1953); *U.S. v. 354 Bulk Cartons*, 178 F. Supp. 847 (D. N.J. 1959).

made explicit and implicit claims about Ariva that are “drug claims” for purposes of the FFDCA. Again, this petition does not argue those claims are the only, or even the primary, basis upon which FDA should assert jurisdiction. Star has, for the time being, decided to market Ariva without those claims. FDA authority to regulate Ariva as a drug remains intact.

Third, central to the Court’s holding in that case was its finding that FDA regulation of the tobacco products at issue would necessarily lead to a ban on conventional tobacco products as customarily marketed, which the Court concluded Congress did not intend. A broad ban on those products is not at stake here. As is discussed above, there is clear precedent for FDA regulation of Ariva under its authority to regulate foods and drugs as it existed before the 1996 regulations, and after the Supreme Court rejected the assertion of authority in those regulations. The Court’s decision in *Brown & Williamson* does not, then, preclude FDA jurisdiction over a product like Ariva.

* * *

The issue is not whether Ariva lozenges might assist smokers to quit or be less hazardous than traditional tobacco products. The verification of these issues should be based on FDA review according to objective standards established by the agency in accordance with its statutory authority, as is the case for other products. Consumers should not be asked to base their decisions on the untested, unverified assertions of the manufacturer.

FDA has been consistent in determining whether it should regulate other unconventional products containing tobacco. To change course now would not only constitute a diversion from consistent FDA precedent, but would also create a regulatory void, and a profit incentive, for companies to continue to attempt to market tobacco in a greater variety of new products intended for human consumption, and to capitalize on nicotine addiction, but with no consideration for

actual safety. It would also allow products that are the functional equivalent of nicotine substitution drugs to be developed and marketed with none of the assurance of safety that the drugs that have gone through the FDA approval process carry. The Supreme Court carved out an exception to FDA's regulatory authority for traditional tobacco products as customarily marketed. Permitting products like Ariva to be marketed without FDA review would dramatically expand that exemption, putting the public at risk in ways never contemplated by the Court or Congress.

Conclusion

Therefore, FDA should classify Ariva as a "new drug" and invite Star to submit a "new drug" application for the product. In the alternative, FDA should classify Ariva as a food containing an unapproved food additive, and should invite Star to submit a food additive petition under the FFDCA.

Environmental Impact

This petition qualifies for categorical exclusion under 21 C.F.R. §§ 25.15, 25.30-25.32, and therefore does not require the preparation of an environmental assessment or an environmental impact statement. In any event, the action requested in this petition will not have any significant effect on the quality of the human environment.

In accordance with the requirements of 21 C.F.R. § 25.15, we assert we are not aware of any extraordinary circumstances.

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.

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Dated: December 18, 2001