IN THE FOOD AND DRUG ADMINISTRATION

Citizen Petitions for Regulation of Ariva	Docket Nos.: 01P-0572 & 02P-0075

COMMENTS IN SUPPORT OF CITIZEN PETITIONS FOR REGULATION OF ARIVA

Submitted by the Attorneys General of California, Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Northern Mariana Islands, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Washington, West Virginia, and Wisconsin

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COMMENTS OF STATE ATTORNEYS GENERAL IN SUPPORT OF CITIZEN PETITIONS FOR REGULATION OF ARIVA

We, the undersigned Attorneys General, are deeply troubled by a new candy-like product, called "Ariva," which contains known hazardous substances and is being rushed to the marketplace without the U.S. Food and Drug Administration's ("FDA") approval. We urge the FDA promptly to notify Star Scientific, Inc. ("Star"), Brown and Williamson Tobacco Company, and any other company planning to market this or any similar product, that they must not do so unless and until the FDA approves the product as safe. We believe that the FDA has the authority to assert jurisdiction over this product and that it is important for the FDA to do so. Ariva is not a traditional tobacco product; it is either a "drug" or an "adulterated food"; and it has a high potential for use and abuse by young people.

Ariva raises serious public health concerns that warrant the FDA's immediate attention. It is a sweetened, mint-flavored product that is the size of a tic tac™ candy. Despite the presence of tobacco, Ariva will be ingested more like a food and is being marketed primarily as a mechanism to get nicotine when and where people can't smoke. It is packaged similarly to some chewing gums, and its packaging features images of blue sky and clean water. Yet, Ariva contains nicotine and other hazardous chemicals. Unlike any traditional tobacco product, Ariva is intended to dissolve completely in the mouth and not be smoked or expectorated. In the wake of the U.S. Supreme Court decision that the FDA may not regulate traditional tobacco products as customarily marketed, even more responsibility has fallen on the states to inform and protect the public regarding traditional products. As explained more fully herein, new nicotine products, such as Ariva, not only are themselves hazardous, but also impede the states' efforts to reduce the suffering and death that traditional tobacco

products cause.

Numerous major public health and medical organizations[1] submitted a petition on December 18, 2001 to the FDA requesting that the agency regulate Ariva ("Health Groups' Petition").[2] On February 15, 2002, GlaxoSmithKline Consumer Healthcare, LP ("GSK") also submitted a petition to the FDA requesting that the agency regulate Ariva and any other flavored candy-like product containing tobacco.[3] Pursuant to 21 C.F.R. section 10.30(d)(2001), the undersigned Attorneys General submit the comments herein in support of these petitions.[4]

Ariva Contains Hazardous Substances and is Not Safe

Ariva has not been tested for health and safety purposes. Because Ariva is digested entirely, Ariva is likely to deliver nicotine and other substances it contains in ways and in levels that have not been evaluated for health and safety. Star has also failed to disclose all the constituents in Ariva. GSK's analysis reveals that Ariva contains potentially toxic and carcinogenic compounds not previously disclosed by Star. These include: xylenes; a suspected furan-related carcinogen; a benzene-related carcinogen; and, another compound thought to be toxic (7-hydroxy-6-methoxy-2H-1-benzoypyran-2-one).[5] This analysis also

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1. These organizations are 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 Center for Tobacco-Free Kids, the National Education Association, the Oncology Nursing Society, Oral Health America, National Spit Tobacco Education Program, and the Partnership for Prevention.

2. The FDA docket number for this petition is 01P-0572.

3. The FDA docket number for this petition is 02P-0075.

4. We seek to supplement, not repeat, the extensive information in the petitions and supplementary materials submitted to the FDA by the petitioners.

5. April 26, 2002 GSK supplemental submission to FDA, related to FDA Docket Nos. 01P-0572 and 02P-0075, at 2.

showed Ariva contains nicotine. The Material Safety Data Sheet[6] on nicotine prepared by nicotine manufacturer Chem Service Inc. warns that nicotine may be fatal if ingested, and that exposure can cause liver and kidney damage, adverse reproductive effects, cardiovascular system injury, delayed adverse health effects, and nervous system injury. [7]

Like a candy lozenge, Ariva will be fully ingested; but, unlike a candy lozenge, there is solid scientific evidence to conclude that Ariva is not safe. Like nicotine gum, Ariva will deliver nicotine orally to consumers; but, unlike nicotine gum, Ariva will be fully ingested, and it has never been tested for safety. Ariva is more like nicotine gum or a candy lozenge than a traditional tobacco product. Protecting the public from a product with the hazardous substances GSK found in Ariva (and any others that might be discovered with more in-depth analysis) falls squarely within the FDA's express mission to protect the public health by ensuring that foods are safe, wholesome, sanitary, and properly labeled; drugs are safe and effective; and there is reasonable assurance of the safety and effectiveness of devices intended for human use.[8]

The FDA Has Jurisdiction Over Ariva

The FDA clearly can assert its jurisdiction over a product such as Ariva, notwithstanding *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), which found that Congress did not intend that the FDA have jurisdiction over traditional tobacco products as customarily marketed. As documented in the Health Groups' Petition and GSK's Petition and supplemental submission, Ariva bears no resemblance to tobacco products as customarily marketed. Rather, Ariva is similar to smoking-cessation products the FDA regulates, such as nicotine gum;[9] to Masterpiece Tobacs (another candy-like product containing tobacco) which the FDA found could not be marketed in the United

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6. Chemical manufacturers must develop or obtain a Material Safety Data Sheet for each hazardous chemical they produce. *See* 29 C.F.R. § 1910.1200(g)(1).

7. *See* http://msds.pdc.cornell.edu/msds/siri/msds/h/q216/q254.html (last visited June 3, 2002). *See also* Cal. Code Regs. tit. 22, § 12000(c) (nicotine recognized to cause reproductive toxicity).

8. *See* 21 U.S.C. § 393(b).

9. Ariva's manufacturer certainly may seek FDA approval to market a safe and effective smoking-cessation product. There is no reason, however, to exempt Ariva from the clinical trials and regulation to which the FDA subjects other nicotine delivery devices such as Nicotrol, Nicorette, and NicoDerm.

States;[10] to GumSmoke, a tobacco chewing gum that the FDA prohibited Star from marketing in 1998;[11] and, to nicotine water, nicotine lollipops, and nicotine lip balm, all of which the FDA recently regulated as illegal drugs.

Brown & Williamson acknowledged that courts should defer to agencies such as the FDA in the interpretation of statutes that the agencies administer, unless Congress has "directly spoken to the precise question at issue," in which case the court is to give effect to the "unambiguously expressed" intent of Congress. (*Id.* at 132.) The Supreme Court explained that deference to agencies such as the FDA is justified

> because "the responsibilities for assessing the wisdom of such policy choices and resolving the struggle between competing views of the public interest are not judicial ones," and <u>because of the agency's greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated</u>.

Brown & Williamson, 529 U.S. at p. 132 (citations omitted; emphasis added). The exemption for traditional tobacco products recognized by *Brown & Williamson* focused narrowly on those products that Congress must have considered over the years. The introduction of a new candy-like product that contains tobacco and nicotine, but is intended to be completely ingested by dissolving in the mouth, is precisely the kind of "ever-changing facts and circumstances" that the Court did not prohibit the FDA from addressing. Thus, the Supreme Court's statements in the *Brown & Williamson* decision underscore the importance of the FDA's using its great familiarity with adulterated foods, drugs which are not traditional tobacco products, and tobacco products making claims of therapeutic benefit, to classify and regulate Ariva.

<u>Ariva Presents Particular Dangers to Young People</u>

Because the product is small and does not emit smoke or strong tobacco odors when used, it would be easy for parents and teachers to be unaware of an adolescent's or child's use of this addictive and hazardous substance. Although Star publicly claims that its product is for current smokers, Ariva has all the features (*e.g.*, mint flavor to cover the unpleasantness for a new user in having tobacco in the mouth, small enough for a new user to manage, relatively low cost) of a product that would appeal to youthful new users.

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10. *See* Attachments F and G to Health Groups' Petition.

11. *See* Attachment E to Health Groups' Petition.

The statements on the Ariva package "Keep away from children and adolescents," "Underage Sale Prohibited," and "THIS PRODUCT IS FOR ADULT TOBACCO USERS ONLY" may serve as an incentive for young people to use the product, because they seek to be more adult. This well-known phenomenon is called the "forbidden fruit" effect. People are more attracted to something when they are told that it is prohibited for certain audiences, especially if they are a member of the audience to whom the restriction applies.[12] Traditional tobacco products have long been successfully marketed to young people by presenting them as an illicit pleasure that is one of the few initiations into the adult world.[13]

The statement on the Ariva package, "As with other oral tobacco products, some users may experience temporary dizziness, heartburn, hiccups or nausea" seems geared to reassure people new to tobacco products. These symptoms are likely to be experienced by people trying tobacco products for the first time; not cigarette smokers, who have built up a tolerance to nicotine's effects.[14] Being assured that the symptoms are "temporary" may persuade a young person experimenting with Ariva not to be alarmed by bodily warning signs such as dizziness or nausea, and to keep using the product until addicted.[15]

Although Star touts its blister packs as "child-resistant," any child who can use a scissors can open a package of Ariva, which looks and tastes like candy. Popular candy is also sold in blister packs, such as Wrigley's Orbit gum and Eclipse gum, and Dentyne Ice gum. Clearly, adolescents can easily open Ariva. Star's reference to "poison control data on the annual incidence of toxicity arising from toddlers' accidental ingestion of tobacco products,"

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12. *See* Joseph R. DiFranza & Tim McAfee, *The Tobacco Institute: Helping Youth Say "Yes" to Tobacco*, 34 The Journal of Family Practice 6, at 694-96 (1992); Brad Bushman & Angela Stack, *Forbidden Fruit Versus Tainted Fruit: Effects of Warning Labels on Attraction to Television Violence*, 2 Journal of Experimental Psychology: Applied 3, at 207-26 (1996).

13. Stanton A. Glantz, *Preventing Tobacco Use - The Youth Access Trap*, 86 American Journal of Public Health 2, at 156-58 (1996).

14. *See* 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) at 594 ("Dizziness, nausea, and/or vomiting are commonly experienced by nonsmokers after low doses of nicotine, such as when people try their first cigarette. However cigarette smokers rapidly become tolerant to these effects."). Available at http://www.cdc.gov/tobacco/sgr_1988.htm.

15. A further concern is that anti-tobacco education programs generally warn children about traditional cigarettes and chewing tobacco, not products such as this.

merely underscores the poisonousness to people of eating products which contain tobacco.[16]

Star Makes Implied and Explicit Health Claims About Ariva

As documented in the Health Groups' Petition and GSK's April 26, 2002 supplemental submission to the FDA, Star has made numerous health claims about Ariva, and the StarCured™ tobacco which the Ariva package misleadingly implies is the only ingredient in Ariva.[17] We note also that the picture of clear blue water and expansive blue and white sky on its packaging, as well as the leaf image on the product itself, convey healthiness. The large image of water and sky on the front of the Ariva package takes up far more space than all of the warnings combined. No health warnings appear on the front of the package. Further, the statements on the package "Keep away from children and adolescents," "Underage Sale Prohibited," and "THIS PRODUCT IS FOR ADULT TOBACCO USERS ONLY" imply that the product is safe for adults.

Ariva's Impact on Critical Public Health Efforts

Widespread availability of Ariva could undermine public health efforts that are saving lives. Most smokers want to quit.[18] Laws and policies creating smoke-free workplaces have substantially reduced smoking prevalence and consumption.[19] These restrictions not only help smokers reduce or cease their tobacco consumption, but they also de-normalize tobacco

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16. *See* Star Scientific, Inc. Comments on Citizen Petition for Regulation of Ariva, FDA Docket No. 01P-0572, May 1, 2002, at 6.

17. The front of the Ariva package states: "20 Cigalett™ pieces (Compressed Powdered Tobacco)," conveying that compressed powdered tobacco is the only ingredient in the pieces. The back of the package says, "The tobacco in Ariva™ is 100% Virginia StarCured ™ tobacco."

18. 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).

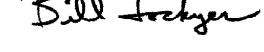
19. Caroline M. Fichtenberg & Stanton A. Glantz, *Smokefree Workplaces Substantially Reduce Smoking: A Meta-Analysis*, BMJ [British Medical Journal] (In Press); John Heironimus, Impact of Workplace Restrictions on Consumption and Incidence (Memo to Louis Suwarna), Phillip Morris U.S.A (January 21, 1992), Bates Range 2045447779/7806, available at http://www.pmdocs.com/getimg.asp?pgno=0&start=0&if=avpidx&bool=2045447779&docid=2045447779/7806&docnum=1&summary=0&sel1= (last visited June 6, 2002).

product use, which supports youth prevention efforts.[20] The California tobacco control program, which focuses on changing community norms regarding the acceptability of tobacco use, has been linked to declines in heart disease deaths and lung cancer.[21] Permitting a hazardous new candy-like tobacco product marketed for "when you can't smoke"[22] would undermine both the de-normalization of tobacco product use achieved by smoke-free areas, and also the support smoke-free laws provide for smokers seeking to reduce their tobacco consumption or quit. Ariva could also undermine efforts to discourage tobacco use among children. Its sweet taste, appearance, and packaging could give children the impression that Ariva presents an acceptable health risk, and permit them to experiment with this product with little risk of getting caught. In short, it could serve as a "gateway" to tobacco use. Failing to regulate Ariva may well cause preventable disease and death.

Request for Action

We applaud the FDA's recent actions to halt the marketing of nicotine water, nicotine lollipops and nicotine lip balm, and now urge the agency also to regulate the nicotine lozenge, Ariva. These nicotine products endanger the public health, including the health of our nation's young people. Accordingly, the FDA should act promptly to subject Ariva to the Agency's oversight, before Ariva becomes more widely available in the market.

Respectfully submitted,



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20. *See* Fitchtenberg & Glantz, *supra* note 19; Louise Ann Rohrbach, *et al.*, *Independent Evaluation of the California Tobacco Control Program: Relationships Between Program Exposure and Outcomes, 1996-1998*, 92 American Journal of Public Health 6, at 975- 83 (2002).

21. *See* Rohrbach, *et al., supra* note 20.

22. This message is fundamentally different from that of nicotine therapies designed and marketed to help people quit smoking.

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