DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

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By Telefax and First Class Mail

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Re: Docket Nos. 01P-0572 and 02P-0075

Dear Messrs. Schultz, Angulo, Myers, Corr, and Bennett and Ms. Cabe:

This responds to your citizen petitions, dated December 18, 2001,[1] and February 15, 2002,[2] respectively, in which you request that the Food and Drug Administration (FDA):

- Classify and regulate Ariva as a "drug" under the Federal Food, Drug, and Cosmetic Act; or in the alternative,

[1] This petition was submitted on behalf of the National Center for Tobacco-Free Kids, the American Cancer Society, the American College of Preventative 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.

[2] This petition was submitted on behalf of GlaxoSmithKline Consumer Healthcare LP.

01P-0572

PDN 1

- Classify and regulate Ariva as a "food" containing an unapproved food additive under the Act.

For the following reasons, we deny your petitions.

Product Description and Claims

Ariva consists of "cigalett" pieces made of compressed powdered tobacco, mint flavorings, and other ingredients. According to its manufacturer, Star Scientific, the tobacco used in Ariva is identical to that used in its snuff products; the only difference is that the tobacco used in Ariva is compressed into tablet form. Star also represents that the mint flavorings used in Ariva are the same flavorings used in traditional chewing tobacco, snuff, and cigarettes.

Ariva's label makes the following claims:

- "All tobacco products—including Ariva™--contain nicotine, an **addictive** substance." (emphasis in original)

- "When you can't smoke.™"

Jurisdiction

In 1996, FDA promulgated regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents. 61 Fed. Reg. 44396 (Aug. 28, 1996). The regulations asserted jurisdiction over cigarettes and smokeless tobacco as drug/device combination products under the Federal Food, Drug, and Cosmetic Act ("the FDCA"). The legal basis for these regulations was subsequently challenged by members of the tobacco industry.

In *Food & Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), the Supreme Court determined that these regulations contravened the clear intent of Congress to exclude certain tobacco products from FDA's jurisdiction. *Id.* at 132. The Court concluded that FDA has no jurisdiction over "tobacco products as customarily marketed" (*id.* at 156) because "they simply do not fit" within the FDCA's regulatory scheme. *Id.* at 143. The Court recognized that "customarily marketed" tobacco products do not include products for which claims of therapeutic benefit, including "drug claims" or "health claims," are made. *Id.* at 127, 158-59.

In reaching its decision, the Court also focused on the comprehensive legislative scheme developed by Congress to regulate cigarettes and smokeless tobacco, which includes the Federal Cigarette Labeling and Advertising Act, 21 USC §§ 1331 et. seq., and the Comprehensive Smokeless Tobacco Health and Education Act (CSTHEA), 21 USC §§ 4401 et seq. The CSTHEA defines "smokeless tobacco" as "any finely cut, ground, powdered, or leaf tobacco that is intended to be placed in the oral cavity." *Id.* § 4408(1). The legislative history does not address this definition, and the implementing regulations essentially track the language of the

statute, adding only that "smokeless tobacco products" include snuff, chewing tobacco, and plug tobacco. 16 CFR § 307.3(f).

Based on the evidence submitted by the petitioners, FDA has determined that Ariva meets the definition of "smokeless tobacco" in the CSTHEA because it is made of powdered tobacco "intended to be placed in the oral cavity." Moreover, FDA believes that, based on the information available to it at this time, it is precluded from asserting jurisdiction over Ariva as currently marketed because it is a "customarily marketed" tobacco product within the meaning of *Brown & Williamson.* Accordingly, FDA denies the petitions.

Sincerely,

John M. Taylor, III
Associate Commissioner for Regulatory Affairs