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April 26, 2002

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

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

Dear Sir or Madam:

On February 15, 2002, GlaxoSmithKline Consumer Healthcare, LP ("GSK") submitted a citizen petition requesting the Food and Drug Administration ("FDA") to notify Star Scientific, Inc. ("Star"), Brown and Williamson Tobacco Corporation, and other tobacco companies that they may not market flavored candy-like products containing tobacco until the agency has authorized the use of tobacco in such products under Section 409 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 348. On December 18, 2001, the National Center for Tobacco-Free Kids and a number of other public health organizations urged FDA to restrict marketing of these products under the drug provisions of the FDCA or, in the alternative, as adulterated food products. In this supplement to the dockets established by these petitions (Docket Nos. 02P-0075 and 01P-0572), GSK includes additional information that further supports such regulatory action by FDA.

At the outset, GSK must emphasize that Star has, during the past six months, vigorously sought to market its candy-like product containing tobacco, Ariva™, on a national basis as quickly as possible. In a March 29, 2002, press release, Star's Vice-President of Sales and Marketing declared:

On January 23 we announced the broader distribution of Ariva (TM) and our expectation to be in at least 10,000 stores by the end of April 2002 – a goal we reached by early March. We are pleased that Ariva (TM) now is available in more than 12,000 stores We anticipate that through expanded distribution agreements, our smokeless tobacco products will be available to consumers in more than 25,000 retail stores by the end of the second quarter."¹

¹ See "Star Scientific, Inc. Reports 2001 Financials Underscoring Shift in Emphasis to Smokeless Products; Three New Independent Directors Elected to Board," March 29, 2002 (attached as Exhibit A).

01P-0572

C2

Dockets Management Branch

April 26, 2002

Page 2

In its annual report released on April 1, 2002, Star goes on to state that it "anticipates greatly expanding the number of stores in which its smokeless tobacco products will be available in 2002" by entering into direct arrangements with several national retail chains and distributors experienced with consumer products.² At the same time, Star has made Ariva available for sale over the Internet through at least one website operated by a distributor of tobacco products.³ Clearly, Ariva is quickly becoming available to consumers across the country.

In light of that fact, and to remove any doubt that FDA has legal authority to regulate Ariva, GSK has undertaken its own analysis of the chemical constituents and physical properties of the product (see Exhibit C). This study demonstrates that Ariva is much more than, as Star suggests, simply a "compressed hard tobacco product." Rather, like a candy or food product, Ariva contains sweeteners (e.g., glucose, fructose, mannitol), flavoring ingredients (e.g., menthol, l-carvone, jasmone, dihydrocarveol, benzaldehyde), anti-oxidants (e.g., butylated hydroxytoluene), and an emulsifier (tripropylene glycol) – ingredients routinely treated by FDA as elements of food products. See, e.g., 21 C.F.R. § 172.515; and 21 C.F.R. § 182.20.

Furthermore, unlike any traditional tobacco product, Ariva is specifically designed to be swallowed as it disintegrates in the mouth – a key factor that led FDA to conclude in 1987 that Masterpiece Tobacs chewing gum is subject to FDA jurisdiction as a food product.⁴ In fact, Ariva contains polymers, buffering agents, and pH modifiers, which prolong the disintegration and dissolution times of each candy-like unit and thereby allow for maximum absorption of nicotine through dissolution in saliva and ingestion into the body. Thus, Ariva contains a discrete assemblage of different ingredients -- not just compressed raw tobacco -- that makes it a food subject to FDA's jurisdiction under the FDCA.⁵

This is not to say, however, that Ariva may be legally marketed in the United States. Indeed, GSK's chemical analysis also confirmed that Ariva contains nicotine and other chemicals typically found in tobacco (e.g., myosmine, nicotyrine). These ingredients and tobacco itself have not been approved by FDA as acceptable food additives, nor are they GRAS

² See Star Scientific, Inc., Annual Report on Form 10-K for the fiscal year ended December 31, 2001 (filed with the Securities and Exchange Commission), at pg. 5 (attached as Exhibit B).

³ Ariva can be purchased on the Internet at the following website address:
www.tobaccobarn.com/dxcart_cigarette_html/dxcart_ariva.html

⁴ See GSK Citizen Petition, at 5; see also Letter from Richard Ronk, Acting Director, Center for Food Safety and Applied Nutrition, FDA, to Stuart Pape, Patton Boggs, September 16, 1987 (attached as Exhibit J to GSK's citizen petition).

⁵ Alternatively, as the public health community has argued, these results also show that Ariva may function as a pharmaceutical lozenge designed to deliver nicotine and, therefore, is subject to the FDCA's provisions governing drug products.

Dockets Management Branch

April 26, 2002

Page 3

or subject to a prior sanction. In addition, while Star has touted Ariva as a safer product than traditional cigarettes because it reportedly contains low levels of tobacco-specific nitrosamines, GSK's study detected other potentially toxic and carcinogenic compounds in the product. These include xylenes, a suspected furan-related carcinogen ("HMF" or 5-(Hydroxymethyl)-2-furfural), benzene-related carcinogen (2,4-bis (1,1-dimethylethyl)-phenol), and another compound thought to be toxic (7-hydroxy-6-methoxy-2H-1-benzopyran-2-one). Accordingly, as GSK requested in its citizen petition, FDA must notify Star and other companies that intend to market candy-like products containing tobacco that such products are adulterated and subject to the seizure, forfeiture, and misbranding provisions of the FDCA. See 21 U.S.C. §§ 331-334.

In closing, GSK notes that other products containing nicotine are beginning to proliferate in the marketplace. Recently, FDA recognized the severity of this problem when it issued warning letters to three pharmacies that were selling "nicotine lollipops" and "nicotine lip balm" over the Internet. Yet, other products containing nicotine remain on the market (e.g., Nicotine Water), while still others may be in commercial development (e.g., Nicotine Candy Cigarettes, Patent No. 6,082,368, issued July 4, 2000). Therefore, just as FDA responded to nicotine lollipops, the agency must also ensure that Ariva and other candy-like products containing tobacco are not marketed in the United States until the manufacturers of such products fully comply with the FDCA.

Thank you for your consideration of this additional information.

Sincerely,

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cc: Lester Crawford, Deputy Commissioner, FDA
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