



1900 K STREET, NW, SUITE 750 WASHINGTON, DC 20006-1163 202-626-3900 F 202-626-3961
BOSTON NEW YORK SAN FRANCISCO WASHINGTON, DC

November 26, 2002

BY HAND

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

**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 behalf of GlaxoSmithKline Consumer Healthcare ("GSK"), we are writing to further supplement the record in the above-referenced dockets. On November 15, 2002, Star Scientific, Inc. ("Star") disclosed certain information about its efforts to distribute and market Ariva™ throughout the United States. As described below, these disclosures make clear that Star's candy-like product containing tobacco is available throughout the country at a variety of different retail locations. Moreover, while Star's disclosures take nothing away from GSK's principal argument that Ariva constitutes an adulterated food product, Star has made certain statements in these documents that provide support for the position of the Campaign for Tobacco Free Kids ("CTFK") and other public health organizations that the product is being marketed as an unapproved drug in violation of the Federal Food, Drug and Cosmetic Act ("FDCA").

Specifically, on November 15, 2002, Star filed its third quarter form 10-Q with the Securities and Exchange Commission and it issued a press release in connection with that filing (see attachments A and B, respectively). Based on these documents, which are accessible at Star's website (www.starscientific.com), it is clear that Ariva is available at a wide variety of stores across the country. Indeed, in its press release, Star's CEO declares that:

"Ariva currently is available in more than 33,000 stores in 48 states. Distribution is directed to the tobacco departments of drug store chains that include CVS, Rite Aid, Osco and Savon, as well as a selection of Wal-Mart and 7-Eleven franchisee stores, other

02P-0075

SUP3

Dockets Management Branch, FDA
November 26, 2002
Page 2 of 3

convenience store chains, Albertson's grocery stores and service station mini-marts.”

To achieve national distribution of the product, Star Scientific states in its 10-Q filing that Ariva is being marketed nationwide through a network of established tobacco distributors and through new distributors. In addition, the Company states that it has sought to introduce Ariva through direct arrangements with several national retail chains and through national distributors experienced with consumer products.

At the same time, while Star adheres to its legal argument that Ariva is like other conventional smokeless tobacco products for the purposes of FDA regulation, the company continues to characterize Ariva as an entirely different type of product in the course of its national roll-out. As GSK demonstrated in its letter of October 1, 2002, to the docket, Star has previously described Ariva as “an exciting innovation,” “a groundbreaking hard tobacco ‘cigalett’,” and a “flagship smokeless tobacco product.” Continuing that marketing distinction, Star’s press release now refers to Ariva as “a break-through product in a completely new product category” Thus, Star continues to try to have it both ways – its argues that Ariva is a conventional smokeless tobacco product for the purposes of the FDCA but a completely new product for the purposes of the marketplace.

Finally, in connection with its issuance of these documents, Star makes an implied smoking cessation claim for Ariva that converts the product from an adulterated food to one that is subject to regulation as an unapproved drug product under the FDCA. In the context of describing the results of a follow-up survey involving Ariva, Star’s representative declared:

“among those contacted who currently use Ariva(TM), 84% indicated that they have decreased daily cigarette intake, and 31.6% have transitioned completely from cigarettes to Ariva(TM). These data support our belief that Ariva(TM) can effectively meet the needs of adult smokers who are looking for an acceptable alternative to cigarettes.”

That statement, particularly when coupled with other information submitted by CTFK demonstrating that Ariva has in certain stores been placed on virtually the same shelves as GSK’s smoking cessation products, provides further support for the public health organizations’ view that Ariva is subject to regulation as an unapproved drug product. Of course, to the extent that Star’s recent statement is not treated as a smoking cessation claim, that does not mean that Ariva is not an adulterated food product under the FDCA.

ROPES & GRAY

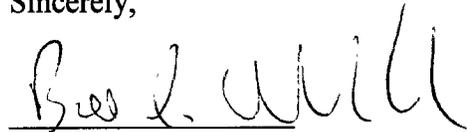
Dockets Management Branch, FDA

November 26, 2002

Page 3 of 3

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce S. Manheim, Jr.", written over a horizontal line.

Alan R. Bennett
Bruce S. Manheim, Jr
Ropes & Gray
1900 K Street, N.W., Suite 750
Washington, D.C. 20006
(202) 626-3900

Attorneys for GlaxoSmithKline Consumer
Healthcare, LP

Enclosures: as stated

cc: Lester Crawford, Deputy Commissioner, FDA
Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, FDA