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MCDERMOTT, WILL & EMERY

July 22, 2002

VIA HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human
Services
5630 Fishers Lane, HFA-305
Room 1061
Rockville, Maryland 20857

Re: Citizens Petitions Requesting FDA to Regulate Ariva™ Compressed Smokeless
Tobacco Cigalett™ (Docket Nos. 01P-0572 and 02P-0075)

Dear Sir or Madam:

By letter dated June 14, 2002, through its counsel Bennett, Turner and Coleman (now Ropes & Gray) GlaxoSmithKline Consumer Health Care, LP ("GSK" or "Petitioner") submitted a letter in the docket in the petitions referenced above to address a prior false statement by GSK in an earlier submission. In that earlier submission, filed on April 26, 2002, GSK stated that Star Scientific, Inc. ("Star Scientific") "...has made Ariva™ available for sale over the Internet through at least one website operated by a distributor of tobacco products". In fact, Star Scientific does not sell Ariva™ through the Internet. The Petitioner only acted after counsel for Star Scientific demanded that it correct the record regarding this false statement.

In its June submission, the Petitioner suggests that Star Scientific misunderstood what it was saying in its earlier comments. The statement at issue, however, is plain on its face and is false. As a result, the Petitioner was forced to acknowledge in its June submission that "Star [Scientific] does not sell Ariva™ over the Internet directly to consumers." The Petitioner attempts to lessen the impact of its false statement by claiming that Star Scientific is not adequately policing the Internet regarding sales of its products by independent retailers. However, GSK not only has failed to substantiate such a claim, but its own investigation shows that Star Scientific has taken reasonable steps to limit Internet sales of its Ariva™ product by third parties.

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Although not relevant to the sale of Ariva™, GSK in its latest submission first notes that a search of Internet sites shows that cigarettes produced by Star Scientific's subsidiary, Star Tobacco, Inc. are available over some Internet sites. Yet one of the exhibits that GSK attaches to its submission is a letter from counsel for Star Scientific to an Internet provider expressing its concerns with the sale of Star Tobacco, Inc. cigarettes over the Internet. In fact, Star Scientific sent identical letters to all Internet providers that it was able to identify who were selling Star Tobacco, Inc. cigarettes over the Internet. GSK quoted extensively from this letter in its submission:

...counsel for Star has provided GSK with a letter that, it says, exemplifies the position that Star routinely takes with respect to the sale of its tobacco products over the Internet. In this letter, Star declares that it does not offer its products for sale over the Internet, because, for among other reasons, 'Internet sales are not sufficiently controlled so as to insure that minors do not have access [to tobacco products] via the Internet.' Moreover, Star's letter advises Internet distributors '[t]o the extent you choose to make cigarettes available over the Internet, you should understand that Star Scientific is in no way endorsing such activity and/or the legality of such practices.' Star also notifies website distributors that it does not authorize them to make any claims relating to its products or any statements suggesting that Star Scientific endorses the sale of its products over the Internet.

The letter underscores Star Scientific's commitment to limit, to the extent possible, sales of its products over the Internet.

While acknowledging that Star Scientific does not sell Ariva™ over the Internet, GSK in a footnote points out that Star Scientific does maintain an Ariva™ website "where individuals over 21 can obtain information about the product." Once, again, GSK seeks to over-play its hand. As GSK is forced to acknowledge, the website, which is informational only, has a screening mechanism to limit access to those over 21. Also, the website prominently notes that Ariva™ is for adult tobacco consumers only and that underage sales are prohibited. GSK's reference to the Star Scientific Ariva™ website only further serves to underscore Star Scientific's commitment to limiting access to Ariva™ to adult tobacco users.

GSK also states that Ariva™ is "increasingly" being sold over the Internet. Yet the one site that GSK had referred to as selling Ariva™ in its April 26, 2002 submission had stopped selling Ariva™ at the direct request of Star Scientific prior to the date on which GSK filed its response. GSK's reference to increasing Internet sales is apparently intended to engender opposition to Ariva™ in the same manner as its initial false statement that Star Scientific was selling Ariva™ over the Internet, or its latest contention that Star Scientific is not adequately monitoring Internet sales. In fact, although Internet sale of tobacco products are not prohibited, Star Scientific has consistently expressed its preference that its products not to be sold over the Internet and has taken reasonable steps to limit such sales.

As noted above, prior to GSK's April 25, 2001 submission, Star Scientific did arrange to have the sale of Ariva™ on the website identified by GSK in its submission (www.tobaccobarn.com/dxcartcigarettehtml/dxcartarivahtrol) halted. In its current submission, GSK identifies four other Internet sites where Ariva™ allegedly could be purchased over the Internet and one website that advertises Ariva™ over the Internet, but where purchases can be made by mail only. Of the four Internet sites that GSK claims are actively selling over the Internet, GSK admits that no product is available through one site, www.aldiscountcigarettes.com. With respect to www.smokeshack.com, following GSK's submission, Star Scientific was able to arrange that sales of Ariva™ over this Internet site be halted. A letter confirming that fact is attached as Appendix 1 as is a product search of this site showing that the term Ariva™ is not currently found on the site.¹ This also is the case with respect to www.cigaretteoutlet.com, where GSK stated that Stonewall™ moist was available for sale. A letter confirming that the vendor would remove this product from the website, and a copy of a website search showing that the product is not available for sale are attached as Appendix 2. The Petitioner also references www.awesomesmokes.com, through which Ariva™ was available for purchase. Ariva has been removed from the website, and Appendix 3 is a copy of the search on the current website which confirms that fact. With respect to the website

¹ As noted in Appendix 1, www.smokeshack.com confirmed that they did not carry any Gumsmoke product which distributors had previously been advised had been discontinued. Appendix 1 also reflects that the reference to Gumsmoke on that website has been removed at the request of Star Scientific, and that a search of the site finds no matches for that term. While GSK notes that Gumsmoke was ordered through this website on May 31, 2002, Star has been advised by the vendor that there was no inventory of Gumsmoke on hand at that time and that a refund was issued to Bruce Manheim, Esq. on June 30, 2002 for a purchase placed on that date.

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www.usasmokeshop.com, Appendix 4 documents Star Scientific's efforts to contact the vendor and to request immediate removal of Ariva from this website.

GSK also asserts that it purchased Ariva™ through the mail from vafco.com. The materials attached to GSK submission from vafco.com reflect that the information on its website contains a notation from material prepared by Star Scientific which notes that the packaging for Ariva™ "also states prominently that Ariva is for adults only and is not for sale to minors...", which underscores Star Scientific's position that all efforts should be made to keep tobacco products out of the hands of minors. Star Scientific has determined that it is Vafco's policy not to make sales to underage customers and that it requires credit card purchases only.

It also is Vafco's policy to send purchasers a form to be completed and returned to Vafco that: (1) lists the purchaser's name, address, telephone and date of birth; and (2) requires the purchaser's signature attesting to the veracity of the age information, and that the purchase is for personal consumption only and not for resale.

As noted by GSK in its submission, Star Scientific has expanded the distribution of Ariva™ following its initial test market. However, in doing so it has sought to insure that the product is distributed in a responsible manner. This has included labeling its product with warnings that go far beyond those required by the Surgeon General. Thus, the back of each pack of Ariva™ contains the following statements:

- There are No safe tobacco products.
- Quitting or Not starting is your best option.
- THIS PRODUCT IS FOR ADULT TOBACCO USERS ONLY.

The front of the Ariva™ package contains a similar statement regarding adult use: i.e., "Underage Sale Prohibited".

Star Scientific has monitored the sale of Ariva™ and has attempted to persuade Internet retailers that have chosen to sell Ariva™ to discontinue such sales. Star Scientific has acted reasonably in marketing and distributing Ariva™ as a smokeless tobacco product and will continue to do so. However, the fact that tobacco products are available over the Internet does not provide a basis for the Food and Drug Administration ("FDA") to

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regulate tobacco products, in general, or Ariva™, in particular. Because the additional comments of GSK state no basis upon which jurisdiction can be assumed by FDA, the comments should not be accorded any weight in considering GSK's Citizen Petitions.

Finally, Star Scientific has recently received Ropes & Gray's July 11, 2002 comments to Docket No. 01P-0572 and 02P-0075 submitted on behalf of GSK. Please be advised that Star Scientific is in the process of preparing a detailed written response to these comments. We maintain the firm belief that Star Scientific's compressed powdered hard tobacco product Ariva™ falls outside of FDA's jurisdiction pursuant to the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000) and that the Petitions are without merit and should be denied.

Respectfully submitted,



David L. Rosen, R.Ph., J.D.

Enclosures

cc: Paul L. Perito, Esq.
Chairman, President and COO
Star Scientific, Inc.

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