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June 13, 2002

VIA FEDERAL EXPRESS

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

Re: Citizen Petition Requesting FDA to Regulate the Ariva™ Compressed Smokeless Tobacco Cigalett™ -Docket No. 02P-0205

Dear Sir or Madam:

The Society for Research on Nicotine and Tobacco ("SRNT" or "Petitioner") submitted a citizen petition dated April 23, 2002, requesting the Food and Drug Administration ("FDA") to regulate the Ariva™ Compressed Smokeless Tobacco Cigalett™. In its submission, the Petitioner referred to Ariva as a "tobacco lozenge," a term that has never been used by Star Scientific Inc., the manufacturer, and a term that incorrectly identifies this smokeless tobacco product. For the reasons set forth below, FDA should summarily deny the SRNT petition.

The Petition Must Be Denied Because it States No Grounds Upon Which FDA Can Lawfully Assert Jurisdiction

The Petition filed by SRNT must be denied because it states no grounds upon which to predicate FDA jurisdiction. The Petitioner nowhere asserts that Ariva Cigaletts meet the definition of any product regulated by FDA pursuant to the provisions of the Food, Drug and Cosmetic Act. ("FDCA"). SRNT does not claim that Ariva is a drug, or a food. It does not claim Ariva is a smoking cessation product. Instead, the Petitioner repeatedly refers to Ariva as a tobacco product, or a smokeless tobacco product, and contrasts Ariva to nicotine replacement therapies. The Petitioner acknowledges that the product is intended for, and used for, tobacco satisfaction. As a tobacco product which is marketed without heatlh or therapeutic claims, Ariva is not subject to FDA jurisdiction, based on the United States Supreme Court's decision in

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FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000). As the Court stated in that case:

> Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme and in the tobacco-specific legislation that it has enacted subsequent to the FDCA. In light of this clear intent, the FDA's assertion of jurisdiction is impermissible. 529 U.S. at 126.

The only basis for jurisdiction alleged by petitioner is the need to regulate the claims supposedly made for the Ariva product. However, the Petitioner is asking FDA to regulate claims that a smokeless tobacco product is less harmful than a smoked tobacco product. FDA does not regulate tobacco products, and cannot regulate their advertising. Star Scientific does not make any claims of therapeutic benefit for Ariva that might permit FDA to assert jurisdiction under *Brown & Williamson* in appropriate circumstances. See 529 U.S. at 127. Jurisdiction cannot be founded on regulating claims for an otherwise unregulated product. The petition must be denied for that reason. Also, as will be demonstrated below, Star Scientific does not even make the claims the Petitioner describes in the petition.

Star Scientific Makes No Health Claims for its Ariva Compressed Smokeless Tobacco Cigalett.

In addition to failing to state a basis for jurisdiction, the argument made by the Petitioner is factually incorrect. Although SNRT characterizes itself as a research society[1], its assertions

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[1] In its petition, SRNT characterizes itself as a scientific body providing scientific information and advice to policy makers. It should be noted, however, that SRNT also has significant relationships with the drug industry, including GlaxoSmithKline, a company that has filed a petition seeking to regulate Ariva™. (The citizen petition filed on behalf of Glaxo is also without merit and should be denied.) For example, in its mission statement, SRNT states that one of its goals is to provide the means whereby the ethical drug industry can obtain expert advice and consultation on tobacco and nicotine-related issues. (see www.srnt.org, "Overview") At least thirteen employees and consultants from Glaxo and its affiliated companies appear on the membership rolls of SRNT (ibid. at "Membership Detail"), and one of the awards made by the Society is the "GlaxoWelcome Young Investigator Award." (ibid. at "News") Glaxo was a sponsor of the recent Annual Meeting of the Society, as well as a sponsor, with two other companies, of a lecture and reception at the meeting. The SRNT membership also includes companies that do contract research for the drug industry, and at least one vendor that lists Glaxo as a supplier. Furthermore, several SRNT members have authored articles or chaired meetings that are reported on the GlaxoSmithKline website for U.S. residents. (www.niconews.com, see, e.g., references to Drs. Hughes and Shiffman). Dr. Shiffman recently reported results on a study he conducted on nicotine lozenges for smoking cessation that was funded by Glaxo. (Archives of Internal Medicine 2002; 162:1267-

regarding the health claims made for Ariva are inaccurate. The Petitioner states that "Ariva advertising either explicitly or implicitly states Ariva is a smokeless tobacco product and smokeless tobacco is less harmful than smoked tobacco." (petition at page 1.) The Petitioner also alleges that a claim is made that "Ariva uses a tobacco stated to have fewer carcinogens than regular tobacco." (petition at page 2.) The only citation made to support the two quoted statements is a reference to a newspaper article, not to the Ariva label. The Petitioner does not, and cannot, cite the Ariva label to support its position, because Star Scientific does not make any claims of therapeutic benefit for Ariva in its labeling. Instead, Star Scientific includes on the Ariva label more warnings than appear on any other tobacco product. The Ariva label does not mention that its tobacco contains fewer carcinogens than regular tobacco, and does not refer to smokeless tobacco being less harmful than smoked tobacco. The labeling does state the following:

> "There are No safe tobacco products."
>
> "Quitting or Not starting is your best option."
>
> "All tobacco products -- including Ariva -- contain nicotine, an addictive substance."

The label also carries, on a revolving basis, one of the three warnings required by the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4402, and the implementing Federal Trade Commission ("FTC") regulations, 16 C.F.R. § 307.2. These Warnings are:

> "THIS PRODUCT MAY CAUSE MOUTH CANCER"

1276.) SRNT points out on its website that it has assisted in the identification of what it describes as pharmacological treatment interventions that have dramatically improved cessation efforts. (www.srnt.org at "administration" SRNT Statement of Policy"). The aforesaid Annual Meeting featured a number of presentations on the nicotine lozenge, a smoking cessation product Glaxo is seeking approval to market in the United States. In addition, in the Spring 2002 SRNT newsletter (Vol. 8, No. 2), current president Harry Lando noted: "There have been discussions and differences of opinion concerning SRNT's role in advocacy and shaping public policy. Although as Bill Corrigan noted in a previous column, we are not a policy or an advocacy organization, I agree with his hope that we can use research to inform policy". Star believes that in filing its petition, SRNT strays far from its stated mission to inform public policy. Instead, it has filed a petition with a federal agency (that lacks jurisdictional authority) that advocates selective regulation of a tobacco product that appears to be perceived as a threat to a product developed by an influential SRNT supporter, i.e. the largest manufacturer of a pharmaceutical nicotine product, Glaxo.

> "THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS" and
>
> "THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES"

Star Scientific also markets a snuff product, Stonewall™, that is made of exactly the same tobacco as that found in Ariva. On the Stonewall label, Star does state that the tobacco used substantially reduces the formation of Tobacco Specific Nitrosamines ("TSNAs"), which are characterized as the major toxins in snuff. However, that statement is followed immediately by a contrasted boxed warning statement:

> "Currently there is no proof that reducing the TSNAs in STONEWALL™ will lower your health risks."

In any materials Star has issued discussing the tobacco in its products, the above statement, or its equivalent has appeared, in order to put the information in the proper context for the consumer.

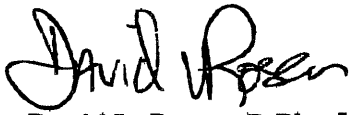
SRNT also cites the low tar/nicotine claims made by companies as an example of the kind of tobacco industry advertising that could mislead consumers regarding risk. The Petitioner then attempts to equate the supposed Ariva claims to said low tar/nicotine claims. As shown above, Ariva makes no claims of any kind, and the effort by SRNT to convince the FDA to regulate the advertising of cigarette like claims falls clearly within the prohibition of *Brown & Williamson*. It is particularly inappropriate for Petitioner to cite the low tar controversy when discussing Star Scientific. SRNT fails to mention, and may not even realize, that Star Scientific recently became the first company to voluntarily remove low tar/nicotine statements from a smoked product. Star did so because of the very NCI Monograph cited by the Petitioner. Star also challenged the rest of the industry to follow its lead in letters to its competitors. None have done so.

Finally, it should be noted that Star Scientific agrees with SRNT about the need for additional research into the relative risk of smoked vs. smokeless tobacco products, and between and among smokeless tobacco products. Star Scientific has continuously supported the need for such research by independent third parties as a basis for determining what claims could be made for smokeless tobacco products. Star has led the move toward reducing the risks in tobacco products. Existing data, including long-term studies undertaken by Swedish Match regarding its low-TSNA tobacco product (Snus) show that this reduction may well decrease the risk to smokers who cannot or will not quit. The research should be pursued. But that fact provides no basis for FDA to assert jurisdiction over Ariva, a smokeless tobacco product that is marketed without claims of therapeutic benefit.

Conclusion

The SRNT petition should be denied. It states no grounds upon which jurisdiction can be assumed by FDA. The stated need to do research on the effect of reducing the toxins in tobacco, while an important public health goal supported by Star, is not a basis for FDA jurisdiction over the Ariva compressed smokeless tobacco Cigalett pieces. SRNT is requesting that the FDA regulate tobacco products, and the claims made for them. The United States Supreme Court has ruled definitively that FDA cannot do so without legislation enacted by Congress.

Sincerely yours,



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