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**MCDERMOTT, WILL & EMERY**

March 5, 2002

**VIA FEDERAL EXPRESS**

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

Re: Notice of Star Scientific, Inc.'s Intent to File Comments  
Concerning Citizen Petition Docket No 02P-0075

Dear Sir/Madam:

We are writing on behalf of our client Star Scientific, Inc. In conjunction with the company and its counsel, we have evaluated the above referenced Citizen Petition concerning Star Scientific's compressed powdered hard tobacco product, Ariva™ Cigalett™ pieces and are in the process of preparing formal comments for submission to the docket. We trust that the Agency will not issue a response to the Petitioners until such comments are received.

We firmly believe 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). The Ariva™ Cigalett™ compressed powdered tobacco product is neither a food nor a food additive as defined under the Federal, Food, Drug and Cosmetic Act. The Petition is without merit and should be denied.

As soon as it is practicable, we will submit substantive comments on the Citizen Petition.

Sincerely yours,



David L. Rosen

cc: Paul L. Perito, Esq.  
Chairman, President and COO  
Star Scientific, Inc.  
Michael F. Cole, Esq.  
Bergeson & Campbell  
R. Bruce Dickson, Esq.  
Paul, Hastings, Janofsky & Walker LLP

02P-0075

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