

ROUTING SLIP
GENERATED BY: HF-40
DATE: JUN 26, 2002

FDA CONTROL NUMBER: 02 3501

TRACER #: **OS #:**

DATE OF CORRESPONDENCE: 06/24/02

DATE INTO FDA: 06/26/02

TO: LESTER M CRAWFORD HF-1

FROM: WILLIAM B SCHULTZ, ZUCKERMAN SPAEDER LLP
MATTHEW L MYERS, CAMPAIGN FOR TOBACCO-FREE KIDS

SYNOPSIS: AMENDMENT TO THE PETITION FILED BY THE CAMPAIGN FOR TOBACCO FREE
KIDS AND OTHERS ON DECEMBER 18, 2001, REGARDING STAR SCIENTIFIC'S
ARIVA TOBACCO LOZENGES (DOCKET NUMBER 01P-0572).

LEAD OFFICE: HFA-305

HOME OFFICE: HF-40

CONTACT/PHONE#: KRISTINA L GODDARD 301-827-2851

COPIES: HF-1 LESTER M CRAWFORD
HF-2 MURRAY M LUMPKIN
HF-40 LAJUANA D CALDWELL

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
----- HFA-305 BUTLERJ	----- NECESSARY ACTION	-----

CAMPAIGN For TOBACCO-FREE Kids®

June 24, 2002

Lester M. Crawford, Jr., D.V.M., Ph.D.
Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

RE: Ariva Tobacco Lozenges Petition (Docket Number 01P-0572)

Dear Dr. Crawford:

This letter serves as an amendment to the petition filed by the Campaign for Tobacco Free Kids ("the Campaign") and others on December 18, 2001, regarding Star Scientific's Ariva tobacco lozenges (docket number 01P-0572). Since the filing of our petition, we have discovered significant, new evidence, regarding the marketing and sale of Ariva, that warrants your consideration and immediate attention.

Specifically, on June 20, 2002, staff from our office entered a CVS pharmacy located at 717 14th Street, NW, Washington, DC and found Ariva tobacco lozenges placed on the shelf separate from every other tobacco product, including every other smokeless product in the store. Instead, it was placed on the same shelf next to an FDA-approved nicotine replacement product, namely NicoDerm CQ and the other smoking cessation products being sold by the store. See Photographs attached to this letter. Staff from the Campaign subsequently visited several other stores, including stores outside the District of Columbia, and found that Ariva was being similarly marketed in those stores as well. This new evidence is relevant because it demonstrates that Ariva is being sold as a smoking cessation aid and is further evidence of Star Scientific's intent to sell Ariva as a drug, similar to other drugs that FDA has approved as smoking cessation aids. This is also consistent with our original petition, in which we stated:

"For purposes of the applicability of the FFDCFA, there is no difference between Ariva and nicotine replacement products (such as nicotine gum) ...that the agency has previously decided to regulate. Like nicotine replacement gum, Ariva will be marketed as a source of nicotine for people to use to address symptoms of nicotine addiction, and, despite the presence of tobacco, it will be sold in food form. Tobacco lozenges therefore fall squarely within FDA's regulatory authority under the FFDCFA."

Ariva Tobacco Lozenges Petition, p. 3. In light of this new and compelling evidence, we reiterate our call for FDA to regulate Ariva as a drug under the Federal Food, Drug and Cosmetic Act. It has been six months since our Petition was filed, and, contrary to the requirements of FDA's regulations (21 C.F.R. § 10.30), we have not received a response. We therefore urge that you place a priority on addressing this problem.

If you have any questions regarding this issue, please do not hesitate to contact us.

Sincerely,



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Attachments







