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November 14, 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 supplement the record in the above-referenced dockets. On April 26, 2002, GSK provided FDA with an analysis of the chemical constituents and physical properties of Ariva™ -- the candy-like product containing tobacco manufactured by Star Scientific ("Star"). Since that time, GSK has undertaken additional chemical analyses of a more recent lot of Ariva. These studies indicate that Ariva has been reformulated so that each cigarett™ is slightly smaller and harder, each contains a more intense mint flavor, and each candy-like unit delivers nicotine in an even more efficient manner. In short, the reformulated version of Ariva even more closely resembles a candy product while, at the same time, allowing for optimal absorption of nicotine. The bases for these conclusions are described in detail in the attached report (Attachment A).

Thank you for your consideration of these comments.

Sincerely,

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02P-0075

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