Bernard A. Schwetz, D.V.M., Ph.D.
Acting Principal Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Schwetz,

The Society for Research on Nicotine and Tobacco would again suggest to the FDA the need for and urgency to regulate Eclipse and other products that claim or infer to reduce exposure to tobacco toxins. Enclosed is a copy of our prior letter to former FDA Commissioner Henney on this matter.

We are reiterating this request for two reasons. First, the recent findings of the National Academy of Science’s Institute of Medicine report, “Clearing the Smoke.” This report summarized research around Eclipse and Eclipse-like products and concluded that such products “have not yet been evaluated comprehensively enough...to provide a scientific basis for concluding they are associated with a reduced risk of disease” and “the net impact on the health of the population as a whole [of Eclipse-like products] could, in fact, be negative.”

Second, recent scientific findings suggest Eclipse might present a new harm via exposure to glass fibers from Eclipse. Yet RJR has not warned consumers of this.

Third, since we last wrote even more reduced risk products have been either marketed or are in development. First, RJR has expanded their market to direct-to-consumer sales in 1700 retail outlets in the Dallas-Ft Worth area. Star Scientific has marketed a new cigarette it claims has reduced carcinogens “Vantage”, Philip Morris has introduced a “reduced smoke” product (Accord) and Brown and Williamson and Vector Group are developing reduced risk cigarettes. All this activity in the last few months clearly indicates, that this issue will not go away and that FDA urgently needs to take a stand about regulation of these products before its credibility is seriously questioned.

Sincerely,

John R. Hughes, M.D.
Chair, Policy Committee, SRNT

7th Annual Meeting • March 23-25, 2001 • Sheraton Seattle Hotel and Towers • Seattle, Washington