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April 23, 2002

*Lee D
5/3/02*

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

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- Ann McNeill, PhD
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- Leslie Schuh, PhD
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- Mitchell A. Nides, PhD
Development Committee

Dear Dr. Crawford,

The Society for Research on Nicotine and Tobacco (SRNT) petitions the Food and Drug Administration (FDA) to regulate Omni and Advance cigarettes. We are also submitting similar petitions on Ariva tobacco lozenges and Nicotine Water. In addition, we have attached a similar petition we sent to the FDA on Eclipse in 2000.

- Joy M. Schmitz, PhD
Chair, Program & Training Council
- Thomas Eissenberg, PhD
2002 Program Committee
- Janine Pillitteri, PhD
Training Committee

SRNT is composed of over 600 of the leading scientists researching nicotine and tobacco issues in the US and 33 other countries. Many of our members have served on WHO, US FDA and other governmental/public organizational committees. One of SRNT's major missions is to provide scientific information and advice to policy makers.

- David Abrams, PhD
Chair, Publications & Communications Council
- Gary Swan, PhD
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Our reasons for urging the FDA to regulate these products are similar to those outlined in our Eclipse letter attached and include:

- Maxine L. Stitzer, PhD
Chair, Scientific Liaison & Public Policy Council
- Marina R. Picciotto, PhD
Scientific Liaison Committee
- John Hughes, MD
Public Policy Committee

- Traditional cigarettes are known toxic nicotine delivery products that are widely available and cause a huge amount of harm. Thus, we would reiterate the continuing and urgent need for FDA to regulate traditional cigarettes
- The current scientific database suggests it is feasible to develop nicotine delivery and tobacco products that are less toxic than current cigarettes. As the Institute of Medicine concluded, under the appropriate conditions, such products could reduce the risk of tobacco use.
- Implicit in Omni (www.omnicigs.com) and Advance (www.starscientific.com) advertising is that these products are less harmful than smoking traditional cigarettes. Although this may be true^{1,2}, we are unaware of a comprehensive scientific analysis of the magnitude of this risk reduction, how much risk remains in using Omni and Advance and the comparative risk in using these products vs traditional cigarettes and nicotine replacement therapies³.
- Such an analysis is important because smokers do believe and often overestimate health claims made by the tobacco industry. For example, a recent NCI report⁴ concluded that most smokers believe low tar/nicotine cigarettes are safer even though these products make only vague implicit health claims in their advertising.

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The NCI report also conclude the health benefits of low tar/nicotine cigarettes are either non-existent or very small⁴. Finally, recent scientific^{5, 6} and industry documents⁷ suggest the marketing of low tar/low nicotine cigarettes has undermined many smokers intentions to stop smoking.

- Omni and Advance use a tobacco stated to have fewer carcinogens than regular tobacco⁸⁻¹¹. However, whether this claim is true for humans using this tobacco and whether this would result in less risk is unclear. For example, machine-testing data on carcinogens must be interpreted cautiously because experience with low tar/nicotine cigarettes clearly shows that people do not smoke like machines do⁴.
- New products can produce unexpected new risks. For example, Eclipse increases carbon monoxide (CO) levels compared to smoking traditional cigarettes¹² and produces inhalation of fiber glass particles¹³
- The availability of Omni and Advance along with implicit or explicit claims of it being a safer cigarette might increase initiation of smoking or undermine motivation for stopping smoking³. We know of no studies on this.

In summary, SRNT believes there are many unanswered questions about the impact of Omni and Advance on public health. Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Omni and Advance so that the policy mistakes that were made with low-tar/low-nicotine cigarettes are not repeated.

Sincerely,

John R. Hughes, M.D.
Chair, Policy Committee
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May 3, 2002

Ms Jennie Butler
 Dockets Management Branch
 Food and Drug Administration
 5630 Fishers Lane, Room 1061
 Rockville, MD 20852

Re: SRNT petitions on Omni/Advance, Arriva and Nicotine Water

Dear Ms Butler,

I certify that, to the best of my knowledge, the above three petitions includes the pertinent information relevant to the petition, favorable or not. Since we are not requesting approval of a food or product or that a food be categorized as GRAS, we do not believe an environmental impact statement is needed.

Attached are the Eclipse letters left out of the above petitions.

Sincerely,

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

Encl.



#53

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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.

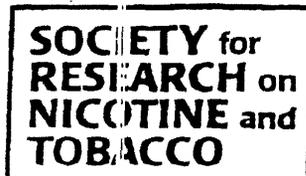
We are reiterating this request for two reasons. First, the recent findings of the National Academy of Science's Institute of Medicine report, "Clearing the Smoke." This report summarized research around Eclipse and Eclipse-like products and concluded that such products "have not yet been evaluated comprehensively 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



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June 16, 2000

Jane Henney, M.D.
 Commissioner
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

Re: Regulation of Eclipse

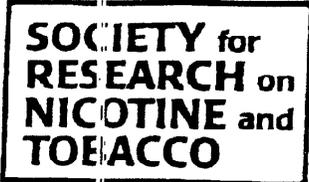
Dear Dr. Henney,

The Society for Research on Nicotine and Tobacco (SRNT) urges The Food and Drug Administration to review the health claims RJ Reynolds is making for their Eclipse product. We believe there is insufficient and contrary scientific results to support these claims and thus FDA should institute some form of regulatory procedures over Eclipse.

Our society consists of 600+ of the leading scientists in tobacco and nicotine research in the US and 33 other countries; thus, SRNT is the largest repository of scientific information in the world. One of SRNT's major missions is to provide scientific data and advise to policy makers.

Our reasons for urging FDA to review Eclipse health claims are as follows:

- Smokers do believe and often overestimate health claims made by the tobacco industry. For example, a recent NCI/ Presidential Commission report ¹ (and other studies ²) concluded that most smokers believe low tar/nicotine cigarettes are safer even though these products make only vague implicit health claims in their advertising. The NCI report (and other reports ³) also conclude the health benefits of low tar/nicotine cigarettes are either non-existent or very small. Finally, recent scientific ^{2,4} and industry documents ⁵ suggest the marketing of low tar/low nicotine cigarettes has undermined many smokers intentions to stop smoking.
- Although there are data that Eclipse delivers fewer carcinogens than regular cigarettes, ⁶⁻¹⁰ there are problems with these data. For example, machine-testing data ⁶⁻⁸ must be interpreted cautiously because experience with low tar/nicotine cigarettes clearly shows that people do not smoke like machines do. ³ To our knowledge, there are only two published studies of carcinogen exposure in



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humans using Eclipse.^{9:10} These studies used small samples, short durations of exposure and were conducted by the tobacco industry.

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Executive Director

- Both an independent study¹¹ and an industry study¹² found that use of Eclipse increased carbon monoxide (CO) levels compared to smoking traditional cigarettes. This is important as increased CO is linked to cardiovascular disease¹³ and smokers are more likely to die of tobacco-induced cardiovascular diseases than of tobacco-induced cancers¹⁴.
- Eclipse exposes smokers to inhalation of fiber glass particles;¹⁵ thus, Eclipse may add a new risk of cancer and lung diseases.
- It is unclear how Eclipse will be used. The only study of the use pattern of Eclipse did not present Eclipse in the manner that RJR is pursuing.¹¹ Smokers might substitute Eclipse for cigarettes. On the other hand, they might use Eclipse solely to avoid smoking restrictions and just add Eclipse use to their ongoing daily consumption of cigarettes. If the later is true, Eclipse could actually increase risk.
- The availability of Eclipse along with claims of it being a safer cigarette might increase initiation of smoking or would undermine motivation for stopping smoking. Although an initial study suggests that Eclipse does not undermine motivation to quit,¹¹ this study lacked an adequate control group to clearly answer the question.

In summary, SRNT believes there are many unanswered questions about the validity of the health claims made by Eclipse.^{16:17} In fact, we believe the availability of Eclipse could result in a net worsening of public health due to increased CO levels, glass inhalation, higher rates of initiation of smoking, or lower rates of cessation of smoking. In addition, other cigarette substitutes (e.g. Accord) and "safer tobacco" products (e.g. Star Tobacco) are likely to make health claims in the not too distant future. Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Eclipse so that the policy mistakes that were made with low-tar/low-nicotine cigarettes are not repeated with Eclipse and other smoking products making health claims.

Sincerely


 John R. Hughes, M.D.
 Chair, Policy Committee
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cc: Geoff Mumford
 Judy Wilkenfeld
 SRNT Office
 Bill Corrigan

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