SOCIETY FOR RESEARCH ON NICOTINE AND TOBACCO

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

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.

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.

Our reasons for urging the FDA to regulate these products are similar to those outlined in our Eclipse letter attached and include:

- 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 therapies[3] .
- Such an analysis is important because smokers do believe and often overestimate health claims made by the tobacco industry. For example, a recent NCI report [4] 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 also conclude the health benefits of low tar/nicotine cigarettes are

either non-existent or very small[4]. Finally, recent scientific[5] [6]and industry documents[7] 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 tobacco[8-11]. 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 do[4] .
- New products can produce unexpected new risks. For example, Eclipse increases carbon monoxide (CO) levels compared to smoking traditional cigarettes[12] and produces inhalation of fiber glass particles[13]
- 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 smoking[3]. 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
SRNT

Reference List

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