SOCIETY FOR RESEARCH ON NICOTINE AND TOBACCO

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April 23, 2002

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 Ariva tobacco lozenges. We are also submitting similar petitions on Omni and Advance cigarettes and Nicotine Water. In addition, we have attached two similar petition we sent to the agency on Eclipse. We are disappointed that no apparent action has been taken regarding Eclipse.

SRNT (www.srnt.org) 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, 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 Ariva are similar to those outlined in our Eclipse petition and include the following:

- 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 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.
- Ariva advertising either explicitly or implicitly states Ariva is a smokeless tobacco product and smokeless tobacco is less harmful than smoked tobacco.[1] Although the latter may be true, we are unaware of a comprehensive scientific analysis of the magnitude of this risk reduction, how much risk remains in using smokeless tobacco and the comparative risk in using smokeless vs nicotine replacement therapies.[2] The recent Institute of Medicine report stated such information is necessary to allow promotion of smokeless as a substitute for cigarettes and outlined the types of research that would need to be done to allow such promotion.

- Also implicit in Ariva advertising (e.g. "for use in situations in which smoking is not allowed") is that the product would mitigate withdrawal symptoms and craving. We are unaware of any data to support this implication.
- Such an analysis is important because smokers do believe and often overestimate health claims made by the tobacco industry. For example, a recent NCI Monograph[3] 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 concluded the health benefits of low tar/nicotine cigarettes are either non-existent or very small.[3] Finally, recent scientific[4;5] and industry documents[6] suggest the marketing of low tar/low nicotine cigarettes has undermined many smokers intentions to stop smoking. We fear the same may be true for Ariva
- Ariva uses a tobacco stated to have fewer carcinogens than regular tobacco.[1] However, this claim has not been verified. A recent Institute of Medicine report has outlined the types of evidence necessary to permit a claim of reduced risk.[7] For example, relying on machine-testing data alone is problematic because experience with low tar/nicotine cigarettes clearly shows that machines testing can be subverted and its results are not generalizable to human smoking.[3] To our knowledge, there are no published studies of carcinogen exposure in humans using the tobacco in Ariva.
- New products can produce unexpected new risks. For example, light cigarettes increase adenocarcinoma of the lung[3] and Eclipse increases carbon monoxide (CO) levels[8] and produces inhalation of fiber glass particles;[9] a comprehensive analysis of any risks by Ariva is needed.
- It is unclear how Ariva will be used. If smokers use Ariva as advertised; i.e., to avoid smoking restrictions, they may simply add Ariva exposure to their ongoing daily consumption of cigarettes. If this were true, Ariva would actually increase risk for smokers.
- The availability of Ariva along with implicit or explicit claims of it being safer than cigarettes might increase initiation of smoking or undermine motivation for stopping smoking.[7] The Institute of Medicine report also raised this concern.

In summary, SRNT believes there are many unanswered questions about the impact of Ariva on public health Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Ariva so that the policy mistakes that were made with low-tar/low-nicotine cigarettes[3;7] are not repeated .

Sincerely,

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

cc: SRNT Executive Committee
SRNT Policy Committee

Reference List

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