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

SRNT ([www.srnt.org](http://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 Nicotine Water 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 nicotine delivery 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<sup>1</sup>.
- Nicotine Water ([www.nicotinewater.com](http://www.nicotinewater.com)) advertising either explicitly or implicitly states it is less harmful than smoked tobacco; e.g. it states "nicotine water was conceived as a healthier alternative to cigarettes." Although this may be true,<sup>2</sup> we are unaware of a scientific analysis of the magnitude of this risk reduction, how much risk remains in nicotine water and how this risk compares to both cigarettes and nicotine replacement therapy. The recent Institute of Medicine report stated such information is necessary to allow promotion of a product as a substitute for cigarettes

and outlined the types of research that would need to be done to allow such promotion<sup>1</sup>.

- Also explicit in Nicotine Water advertising is that the product would mitigate withdrawal symptoms and craving and could be used by smokers who “cannot smoke at their places of work” or “who wish to quit smoking.” Unlike existing medications, we know of no published data on the efficacy of Nicotine Water on these either of these outcomes.
- A scientific analysis of the reduction in risk from Nicotine Water is important because smokers do believe and often overestimate health claims. For example, a recent NCI Monograph<sup>3</sup> 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.<sup>3</sup> Finally, recent scientific<sup>4;5</sup> and industry documents<sup>6</sup> 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 Nicotine Water.
- New products can produce unexpected new risks. For example, light cigarettes increase adenocarcinoma of the lung<sup>3</sup> and Eclipse increases carbon monoxide (CO) levels<sup>7</sup> and produces inhalation of fiber glass particles;<sup>8</sup> a comprehensive analysis of any risks by Nicotine Water is needed.
- It is unclear how Nicotine Water will be used. If smokers use Nicotine Water as advertised; i.e., to avoid smoking restrictions, they may simply add nicotine exposure to their ongoing daily consumption of cigarettes. If this were true, nicotine could actually increase risk for smokers.
- The availability of Nicotine Water along with implicit or explicit claims of it being safer than cigarettes might increase initiation of smoking or undermine motivation for stopping smoking.<sup>1</sup> The Institute of Medicine report also raised this concern.

In summary, SRNT believes there are many unanswered questions about the impact of Nicotine Water on public health. Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Nicotine Water so that the policy mistakes that were made with low-tar/low-nicotine cigarettes<sup>1;3</sup> are not repeated.

Sincerely,

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

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