

March 28, 2006

Associate Director for Communications Office of the Director National Institutes of Health Building 1, Room 344 9000 Rockville Pike Bethesda, MD 20892

Re: <u>Information Quality Request for Correction</u>

Dear Sir or Madam:

I respectfully submit the following Information Quality Request for Correction.

1) Detailed description of the material proposed for correction, included where located on website etc.

The following website contains information regarding smokeless tobacco ("spit tobacco") that we believe should be corrected

 $\underline{http://www.nidcr.nih.gov/HealthInformation/DiseasesAndConditions/SpitTobacco/SpittingIntoTheWind.htm}.$

The specific objectionable material appearing on this website states as follows:

"What's Really in it For You?



- Nicotine (addictive drug)
- Polonium 210 (nuclear waste)
- Formaldehyde (embalming fluid)
- Cancer-Causing Chemicals
- Radioactive Elements

These are just some of the ingredients in dip and chew. Spit tobacco is not a safe alternative to cigarettes. The toxic chemicals can damage your gums. They also can cause cancer."

2) The specific reasons for believing that the information does not comply and supporting documentation.

The information provided on the site and the manner in which it is presented is misleading. With respect to "radioactive elements" generally and specifically, "Polonium-210 (nuclear waste)", the major source of Polonium-210 is food. In fact, over 75% of exposure to Polonium-210 comes through food products. It comes from soil

transfer, as a component of fertilizer and air deposition. Air and water also contain this element. To our knowledge, there is only one published report that evaluated the presence of radioisotopes in U.S. smokeless tobacco products. Hoffmann et al., in a paper published in 1986, measured Polonium-210 levels in five brands of U.S. commercial snuff. Specific radiation levels for each of the five brands were: 0.64, 1.22, 0.33, 0.16, 0.18 pCi/g. Polonium-210 is of interest because it decays to radon, a radioactive gas that is considered to be a human carcinogen (NTP 2000). Tso et al. in a 1966 paper theorized that radioactive Polonium-210 originated in U.S. tobacco from soil that had been fertilized with phosphates rich in Radium-226. Martell, in a 1974 paper theorized that Polonium-210 in tobacco products originated from airborne particles that were taken up by the glandular hair of the tobacco leaf.

The human health risk from Polonium-210 in snuff is insignificant. Assuming the use of 12 grams of snuff/day (an acceptable average use of snuff per day, as reflected in a 1988 paper published by Hatsukami et al.), and a Polonium-210 concentration in snuff of 1.22 pCi/g (Hoffmann et al. 1986), a snuff user would be exposed to 5,344 pCi/year of radiation. This is less than 1/1500th of the annual 10⁷ pCi/year allowable occupational exposure limit to Polonium-210 (NRC 2000).

Therefore, to suggest as the above website does, that radioactive elements and so-called nuclear waste are found in smokeless tobacco is misleading because their presence in smokeless tobacco are so low as to create no health impact on humans.

With regard to the suggestion that smokeless tobacco contains formaldehyde ("embalming fluid"), this is similarly misleading. Formaldehyde is naturally produced in the body in small quantities, is present in the air, food, cosmetics and medicine. Levels in food can vary but fruits, vegetables, meat and dairy products can all contain formaldehyde. For example pears can have levels of 60 ppm, pork 20 ppm, and frozen cod 20 ppm. It is not surprising then, that trace amounts of formaldehyde may be present in smokeless tobacco, but at levels no higher than found in foods.

As with your agency's comments regarding radioactive elements and Polonium-210, it is therefore misleading to include the unqualified comment that formaldehyde, or as you state "embalming fluid", is present in smokeless tobacco when the trace amount present can have no greater impact on humans than they would be exposed to in foods.

In regard to "Cancer-Causing Chemicals" and "Radioactive Elements" we cannot be sure specifically what you are referencing. However, no chemicals or elements are present in our products that do not occur naturally in many food products.

Finally, a poison symbol is placed beside this ingredient list. The overall impression of this display is misleading to our consumer and presents an image of the ingredients, quality and safety of our product that is not accurate.

3) Suggested recommendations for what corrective action(s) should be taken.

We request that the information be removed from this website.

4) A description of how the person requesting correction is affected by the error.

As a manufacturer of smokeless tobacco products this misleading information prevents our consumers from getting accurate information about our products. As a result, adult consumers are less able to make informed decisions about the type of tobacco products that they use. To put this in some perspective, consider the following statement by Britain's Royal College of Physicians in December 2002, in a paper titled "Protecting Smokers, Saving Lives": "As a way of using nicotine, the consumption of noncombustible tobacco is of the order of 10–1,000 times less hazardous than smoking, depending on the product. Some manufacturers want to market smokeless tobacco as a 'harm reduction' option for nicotine users, and they may find support for that in the public health community."

In terms of the "real world" impact of consumers, who if provided with accurate information regarding smokeless tobacco, might switch from cigarette smoking to smokeless tobacco if they cannot quit smoking on their own or through the use of Nicotine Replacement Therapy, the following should be considered: "We find that if all current male smokers begin using smokeless tobacco, life years for the current population of adult males in the United States could be extended by approximately 18 million years. ... [Even] if we could reach an attainable goal of bringing smokeless use rate up to Sweden's [approximately 20 percent of the male population], approximately 9.4 million smokers would begin using smokeless tobacco. The number of life years saved would be about 2.16 million."

Ault RW, Ekelund RB, Jr., Jackson JD, Saba RP. "Smokeless tobacco, smoking cessation and harm reduction: an economic analysis." *Applied Economics* 2004; 36: 17-29.

It is my company's view that any government website discussion of smokeless tobacco, in order not to be misleading and inaccurate by making blanket statements that smokeless tobacco is not "safe", should, at a minimum put the relative risk of smokeless tobacco in the proper perspective.

Please do not hesitate to contact me if there is anything further I can provide.

Best Regards,

Gerard J. Roerty, Jr.

Vice President, General Counsel & Secretary

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