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Ms. Caryn Cohen
Office of Science, Center for Tobacco Products
Food and Drug Administration
Document Control Center, Bldg. 71, Rm. G335
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Re:

Written Submission to the Food and Drug Administration Tobacco Products Scientific Advisory Committee (TPSAC) on the modified risk tobacco product application (MRTPA) for Copenhagen Snuff by U.S. Smokeless Tobacco Co., LLC (USSTC).

Background

Citizens Against Government Waste (CAGW) is a private, nonpartisan, nonprofit organization representing more than one million members and supporters nationwide. CAGW's mission is to eliminate waste, mismanagement, and inefficiency in government. Founded in 1984 by the late industrialist J. Peter Grace and syndicated columnist Jack Anderson, CAGW is the legacy of the President's Private Sector Survey on Cost Control, also known as the Grace Commission.

We are pleased to provide a copy of our comment re the MRTPA for Copenhagen Snuff Fine Cut to the TPSAC. CAGW urges the committee to recommend that the FDA issues a marketing order for the MRTPA submitted by U.S. Smokeless Tobacco Co., LLC for Copenhagen Snuff Fine Cut.

Comment

Overregulation poses a significant threat to tobacco harm reduction efforts and awareness, as does governmental hesitancy about lower-risk tobacco products. If adult smokers are to migrate to products that fall lower on the continuum of risk, accurate and reliable information must be made available to them. The application for a modified risk claim on Copenhagen Fine Cut Snuff offers an opportunity to embrace a future of tobacco harm reduction by authorizing a modified risk claim for the first time.

As the FDA and public health authorities around the world have acknowledged, not all tobacco products pose the same risk, and reduced risk products offer a chance to save lives, improve public health, and save taxpayer dollars while bringing about a more effective, efficient government. For several key reasons, this MRTPA stands out as an ideal opportunity to realize this potential.

First, as many adult cigarette smokers are also current users of moist smokeless tobacco, there is already a strong foundation for improved harm reduction outcomes. These Americans already use a product that is less harmful than cigarettes; the only question is whether they can be guided to switch entirely to moist smokeless tobacco. USSTC's proposed modified risk claim makes clear that total replacement of cigarettes is required for risk reduction. Users of more than one tobacco product are key targets for harm reduction, and this narrow proposed modified risk claim has the potential to be particularly effective for dual users.

Second, the proposed MRTPA is grounded in strong science and backed up by examples in real life. Sweden has the lowest smoking rate, and the lowest lung cancer rate, in Europe, because it has essentially replaced cigarettes with moist smokeless tobacco. The key ingredient for success is awareness; in the U.S., many smokers and dual users erroneously believe that cigarettes and moist smokeless tobacco present equal risks, or even that moist smokeless tobacco poses an increased risk. Only the FDA can determine whether the truth of the potential for harm reduction can be communicated directly to consumers through this modified risk claim.

Third, non-tobacco users are unlikely to begin using moist smokeless tobacco because of a change in warning label. Moist smokeless tobacco is not affected by the problems of underage use and its initiation nearly to the extent that some other tobacco products have been affected. This proposed modified risk claim would not give the impression that smokeless tobacco is without any risk.

This application offers a chance to test a new strategy for tobacco harm reduction that provides accurate information, is directed at current adult smokers and dual users, and, if adopted, could save thousands of lives. The benefits to public health, consumers, and taxpayers would be substantial.

CAGW urges the FDA to approve the MRTPA for Copenhagen Snuff Fine Cut by U.S. Smokeless Tobacco Co., LLC.

Sincerely,

Thomas Schatz