Swedish Match's snus: the first FDA application as modified risk. Good luck!

By ACSH Staff — June 12, 2014

The recently-released deeming regulations by which the FDA proposes to regulate tobacco products and those devices variously known as e-cigarettes, personal vaporizers and mods requires that each product (and perhaps each component) go through a specific approval process. This process can go in one of two directions: those applying for a substantial equivalence approval must prove to the agency's satisfaction that the product is, well, substantially equivalent to a product already on the market as of 2/15/2007; or they must go through a premarket approval process requiring an extraordinarily detailed database showing that not only is the new product less harmful for the individual user/smoker, but that the total population effect will be beneficial, or at least not as harmful. This process, for those companies brave, patient and wealthy enough to undertake it, is expected to consume years and millions of dollars, for an uncertain outcome.

News was just released that the Swedish company known for its smokeless product, snus, which has been marketed for over a century, has applied to the FDA to get that new product approval. The company, Swedish Match, is the biggest seller in Europe of the snus-type smokeless product, which comes in small packets and is kept between lips and gum for ten or fifteen minutes and supplies a satisfactory dose of nicotine to those who crave it. (Similar snus-types are sold in the USA by Altria and RJR). This has been proven effective against smoking in the best possible way: Swedish men have the highest level of smokeless tobacco use in the world, and also the lowest smoking rates in the western world. And of course, they have the lowest rates of smoking-related diseases, thanks to their devotion to snus. Women, not so much, and they have similar smoking and death rates due to smoking as the rest of the EU. (Now, Norway is also gaining ground against the toll of smoking via snus. An ironic fact: snus sales are banned in the EU, except for Sweden; Norway is not in the EU. Don't ask why this is true, there is no reason on earth for it. If you must know, see this: Death by Regulation by the UK's brilliant Clive Bates).

ACSH's Dr. Gil Ross, who has been closely observing the FDA's approach to regulation of reduced-risk products and other aspects of this burgeoning area, had this comment: As anyone
concerned with public health should, we here at ACSH wish Swedish Match well in their quest for FDA approval. It is possible that, given their long history in the smokeless tobacco game, and their substantial assets, they may come out OK on the other side of this process. But the FDA, even granting them good faith in these matters about which I am dubious at best, given their anti-harm reduction deceptions over the past decade has a many-thousand-product backlog of approval-seekers, and they have shown not the slightest inclination to hurry it up. So it will, best case scenario, take some years to get that coveted approval. Meanwhile the good news while the application is pending, chances are business will proceed as usual. And who knows? By that time, some wiser heads at FDA or HHS or OMB may supervene and modify the harsh deeming regulations.