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FDA s historic baby step towards tobacco regulation

By ACSH Staff — June 26, 2013

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At last, as the song goes, the FDA s Center for Tobacco Products (CTP) charged with regulating cigarettes, loose tobacco, snuff, and chewing tobacco by the new law in 2009 has actually done something. Or has it?

Because of the byzantine nature of the Family Smoking Prevention and Tobacco Control Act, the FDA was mandated to review those tobacco products introduced on the market between February 2007 and March 2011, to adjudicate scientifically whether they could remain available, because they were substantially equivalent to older products. Since that rule was promulgated, approximately 4,000 applications have been made for substantial equivalence (SE) permission. Until yesterday, exactly zero determinations had been made, despite a staff of over 100 government workers supposedly focused on those decisions.

So yesterday [2], to great hoopla (emanating almost entirely from the FDA itself), CTP head Mitch Zeller announced the approval of ¦wait for it ¦two new products (well, products substantially equivalent to older products anyway). These two happen to both be Lorillard s Newport cigarettes, without the controversial flavoring menthol found in all other Newports.

Four other applications were rejected, leaving the other several thousand still in limbo. Why were those four found wanting? No one is saying, pleading confidentiality! But the hints have indicated some combination of simple application errors, missing information, or the mysterious ingredient issue. Why has the agency taken so long to do so little? Again, no help forthcoming from the regulators, so don t even ask. The tobacco companies suspect foul play, i.e. that the FDA is slow-walking the evaluations to keep the market free of new products except that the pending SE applications are mostly for products actually on the market already.

ACSH s Dr. Gilbert Ross had this perspective: Whatever just happened is far from what FDA Commissioner Hamburg proclaimed: Historic! Nothing much has happened, period, except some indication that the backlog of applications may start to loosen now.

So what? Precisely because these products-in-waiting are substantially equivalent to older products, by definition nothing much will change for public health whether or not they are OK d by Zeller s folks. However, what would be historic is if the FDA uses commonsense and relative risk assessment to allow reduced-risk nicotine products onto the market without deeming them medicinals requiring onerous, expensive, lengthy clinical trials. On the other hand, effectively excluding e-cigarettes from the market via stringent, low allowable nicotine levels would have the effect of killing smokers and protecting cigarette and pharmaceutical markets. Allowing flexibility in their evaluation would indeed mark a historic, salutary milestone for the FDA and for America s

public health.