# Encourage the FDA to Reject the Tobacco Industry's Good Manufacturing Practices Proposal and to Implement Strong, Meaningful Regulations

The U.S. Food and Drug Administration (FDA) is currently accepting comments on a proposal submitted by the tobacco industry, which requests that the FDA implement a Good Manufacturing Practices (GMP) regulation to govern the manufacturing process for tobacco products and suggests proposed language for such a regulation. Under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the FDA is given the authority to regulate tobacco product manufacturing.[1]

Unsurprisingly, the proposal submitted by the tobacco industry is weak and rife with problems. Chief among those problems is the tobacco industry's attempt to substitute an individual risk standard in lieu of the population-based standard that Congress specified must be met for the FDA to act. Since the passage of the Tobacco Control Act, the tobacco industry has taken every opportunity to assert the argument that the FDA must consider the risk of harm to individuals whenever it takes any action. This would change considerably the standard for FDA action compared to what Congress intended when it created the Tobacco Control Act. The Act creates an aggregate, population-level standard that mandates that the FDA consider a regulation's effect on users and non-users of tobacco products and the likelihood that users will quit and non-users will start using tobacco products. It does not require the FDA to consider the risk of harm that an individual product poses to an individual user. The public health standard is broad and gives the FDA significant authority to act. The tobacco industry would like nothing more than to weaken this standard and it is attempting to use this GMP proposal to further that agenda.

The tobacco industry's proposal also uses vague language to make each provision open to broad interpretation that would inevitably lead to enforcement challenges. Furthermore, the proposal is completely lacking in any enforcement mechanism. On the whole, the proposal represents an attempt to codify industry self-regulation. Given the tobacco industry's long history of deception and product manipulation, self-regulation would have disastrous consequences for public health and the FDA needs to be informed of that deadly potential.

This tobacco industry proposal must be opposed and it is up to the public health community to explain to the FDA why the proposal should be rejected. Consider submitting comments to the FDA that:

- Explain the history of the tobacco industry's behavior. In particular, provide details on the industry's history of deception and manipulation. Information to supplement comments can be found in our publication, *The Verdict Is In: Findings From United*

*States v. Philip Morris*, which provides quotations from Judge Kessler's extensive findings of fact relating to the tobacco industry's decades-long history of deceptive behavior.

- Explain to the FDA the vital importance of using the population-based public health standard to evaluate regulations rather than the individual risk standard proffered by the tobacco industry. The FDA must consider the broad, public health implications of any regulation relating to GMP and any other regulations that it considers in the future.

- Explain to the FDA why it is a bad idea to let the tobacco industry draft the regulations that govern it. The tobacco industry has no incentive to participate in good faith in the creation of meaningful regulations. The history of the industry's behavior and this latest proposal provide evidence of the industry's true intentions.

- Explain to the FDA that any GMP regulation should exercise all of the FDA's statutory authority including: testing of pesticide chemical residue,[2] creation of a stringent variance process that only grants variances upon a showing by the manufacturer that any deviation from GMP will not harm the public health or violate any other provision of the Tobacco Control Act,[3] and the creation of processes that allow the Tobacco Products Scientific Advisory Committee to review any variance applications.[4]

- Explain to the FDA that the Tobacco Products Scientific Advisory Committee should be given a reasonable time to make recommendations on any GMP regulation before a final rule is issued.[5]

*Last Updated: April 2013*

**Notes**

[1] 21 U.S.C. § 387f(e).

[2] 21 U.S.C. § 387f(e)(1)(A).

[3] 21 U.S.C. § 387f(e)(2)(A).

[4] 21 U.S.C. § 387f(e)(2)(B).

[5] 21 U.S.C. § 387f(e)(1)(B)(i).