Congress of the United States
Washington, DC 20515

October 10, 2012

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We are writing to express our concerns with your agency's implementation of the Family Smoking Prevention and Tobacco Control Act of 2009.

In your *Draft Guidance for Industry: Modified Risk Tobacco Product (MRTP) Applications*, several types of animal studies, including addiction studies, were listed as potential means of investigation for companies wishing to prove that certain tobacco products are "safer" than others. The guidance suggests companies can compare the "abuse liability" of MRTPs by conducting studies using "animal models of conditioned place preference (CPP), drug discrimination, and self-administration."

While we acknowledge that this guidance presents recommended tests and not testing requirements, the clear implication is that if a company plans to apply for a designation of lower risk it should conduct the studies that your agency recommends. Our concern is that this draft guidance, if left unchanged, will encourage additional animal-based studies that are unnecessary and potentially misleading.

There is significant scientific evidence that animals are poor models for the testing of tobacco products used by humans. The United Kingdom, Germany, Belgium, and other countries have banned animal tests with tobacco products, while Canada only requires in vitro tests.