

Drug Dependence Clinical Research Program: New Biomarkers for Tobacco Exposure
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Abstract:

The U.S. Food and Drug Administration Center for Tobacco Products (CTP) recently published a list of research priorities deemed most relevant to its responsibility for the regulation of tobacco products. The first priority listed is "understanding the diversity of tobacco products." While extensive data are available on the chemical composition and human exposure to tobacco toxicants for conventional cigarettes, much less is known about new and emerging tobacco products such as snus, electronic cigarettes, and hookah that users may perceive as less harmful than conventional cigarettes. Our funded PSO, DA012393, provides analytical chemistry support to numerous investigators carrying out behavioral and toxicological studies of tobacco, including some relevant to the mission of CTP. Our PSO also develops new biomarkers of exposure, and improved analytical chemistry methods for assessment of exposure to tobacco toxins. In this Revision Application, we are proposing to develop new biomarkers of exposure: (1) the tobacco alkaloid nicotine as a biomarker for tobacco smoke particulate matter (TPM, "tar"), and (2) pseudooxynicotine, the chemical precursor to the tobacco-specific carcinogen 4-(methylnitrosamino)-1-(S-pyridyl)-1-butanone (NNK). In developing these biomarkers, we will analyze urine samples from subjects using new and emerging products: hookah, snus, and electronic cigarettes. We will also analyze urine samples from users of conventional tobacco products: cigarettes, cigars, and oral snuff. We will also analyze new and conventional tobacco products for toxic substances and their precursors. Our application addresses four FDA research priorities (2-5) listed in the FOA for the present program. If funded, we expect that the new biomarkers that we develop will aid the FDA in evaluation of new and emerging tobacco products, enhance the ability of our PSO to support studies relevant to the FDA CTP's mission, as well as advance the field of tobacco exposure assessment. We expect that our analytical chemistry methods will identify substances in tobacco that predict human toxicity, and thus represent possible targets for regulation or development of reduced harm products.