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February 6, 2004

US Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Dockets Management (HFA-305)
5630 Fishers Lane RM 1061
Rockville, MD 20850

Re: Premarket Submission and Labeling Recommendations for Drugs of Abuse
Screening Tests. – Draft Guidance

I am an academican and a practicing board certified forensic toxicologist with more than 30 years experience in the profession. I am also the director of a SAMHSA certified lab and a drug testing consultant to various US government agencies including the armed forces. In the past I have also been a member of the FDA's Clinical Toxicology Devices Panel. Having been recently appraised of the FDA's Draft Guidance to Industry on Drugs of Abuse Screening Tests, I find it necessary to provide my comments.

As proposed, this Guidance would remove the single most important safeguard available for drug screening tests: bundled confirmation. Further, this Guidance removes all distinction between a certified technologist and an anxious parent, between a screening device capable of no better than approximately 95% accuracy and GC/MS testing with accuracy approaching 100%. As proposed, the FDA intends to integrate occasional test settings such as home testing and repetitive test settings such as sports, schools, insurance and rehabilitation centers. I respectfully disagree with this intent as it will not streamline drug screening nor will it meaningfully reduce the relative cost burdens on the end user.

I do not feel that cautionary labeling is a viable substitute for confirmation, preferably GC/MS confirmation. The result of a false positive test has significant adverse potential where school, sports, insurance and employment are concerned. Where mandated, drug screening must be undertaken only when it is both safe and effective. Parents and their children, employers, employees, students and indeed everyone involved in the screening process have the right to expect it to be so. I believe that implementation of this Guidance will undermine drug screening as a preventative/deterrent methodology; leading to serious consequences where inaccurate results will go unconfirmed.

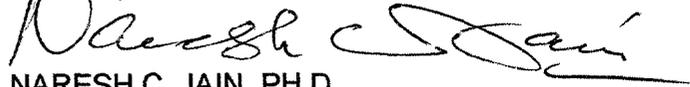
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I am in opposition to this Guidance as it pertains to the omission of confirmation (preferably GC/MS) testing in Workplace and OTC drug of abuse tests. These tests can and will be performed by individuals inexperienced in diagnostic test performance and interpretation, utilizing screening devices; many of which do not offer the accuracy necessary to guarantee both safe and effective application.

Sincerely,



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Laboratory Director

cc: Dr. Donna Bush, SAMHSA