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January 12, 2001

Dockets Management Branch (HFA-305)
Attn: Docket No. 99D-1020
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20850

Dear Ms. Cooper,

Following are the comments of the Drug and Alcohol Testing Industry Association (DATIA) on the Food and Drug Administration's (FDA) draft guidance "Over the Counter Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications". DATIA is an 1,100+ member non profit national trade association representing the entire spectrum of service providers in the drug and alcohol testing industry, including consortia, third party administrators, specimen collectors, medical review officers, laboratories, and testing equipment manufacturers. DATIA's comments on behalf of its constituency are based upon member input, including a survey of the membership.

The main concern that DATIA has with the draft guidance is that it equates workplace testing with home testing. Our members overwhelmingly indicated that workplace drugs of abuse screening tests should not be subject to FDA over-the-counter approval. Experienced and trained specimen collectors/testers conduct workplace drugs of abuse screening tests, not an amateur or layperson as in home testing. The Department of Health and Human Services (HHS), Department of Transportation (DOT), and an increasing number of state laws specifically address who can perform a drug test specimen collection and/or on-site drugs of abuse test. Although not licensed medical personnel, the persons performing these tests are required to have been trained, will soon be required to be certified, and are professionals.

In addition to the distinction between who performs workplace on-site drugs of abuse screening tests, the proposed over-the-counter guidance would significantly hamper scientific and technological advancements in on-site testing. Since any change in the product, drugs tested for, or cutoff levels would result in a new product that would need to go through the over-the-counter approval process, this will slow down introduction of new and more reliable tests into the market. FDA over-the-counter approval costs significantly more and takes much longer than the current premarket clearance that the tests must currently go through. It is for these reasons that only a handful of manufacturers have attempted to get over-the-counter clearance for home drugs of abuse screening tests. To apply these over-the-counter guidelines to workplace drug testing would possibly result in only a handful of manufacturers attempting to complete the approval process – a significant step back for the industry.

DATIA members have stated that they feel the entire draft guidance should not apply to workplace drug testing, however, one specific requirement contained in the draft guidance causes them concern. Our members oppose the requirement for all workplace drugs of abuse urine screening tests to include the fee for a laboratory confirmation test whether or not the confirmation test is performed. The FDA's reason for this requirement appears to be to ensure that all non-negative results are sent for laboratory confirmation, however, the inclusion of the laboratory testing fee into all screening tests does not offer this assurance. This requirement will most likely have the opposite effect of lowering the amount of drugs of abuse screening tests performed since the barrier to entry will be high. Many employers request that their drug testing program use these quick response tests for their ability to provide a near immediate negative result. This saves the employer time and money. For the FDA to require a fee for confirmation testing on all drugs of abuse screening tests would be the same as the DOT requiring that all laboratory drug testing fees also include a fee for testing of the split specimen. The majority of DATIA members who completed our survey on this issue indicated that the fee for confirmation testing should not be included in the fee for on-site drugs of abuse screening tests, but rather the confirmation fee should be paid only when a confirmation test is required and performed.

It is current practice, and included in the HHS draft "Mandatory Guidelines for Federal Workplace Drug Testing Programs", that all non-negative results are sent to a laboratory for confirmation testing. In addition, states and employers commonly base their drug free workplace programs after the HHS guidelines thereby ensuring that the majority of drug free workplace policies incorporating point of collection screening tests will include protocols for sending non-negative results for confirmation testing.

DATIA has continually worked towards increasing the professionalism within the drug and alcohol testing industry through education, training, and effective regulation. The majority of our members do not see where these draft guidelines will result in more accurate and reliable drugs of abuse screening tests. In addition, important questions have been raised by our members as to the jurisdiction of the FDA in issuing these draft guidelines for over-the-counter clearance of workplace drugs of abuse screening tests. We encourage the FDA and the Executive Branch to seriously look at these issues.

We thank you for the opportunity to provide these comments to you. Please feel free to contact me at any time to further clarify the views of DATIA and our members.

Sincerely,

Laura E. Norfolk
Executive Director