

September 30, 2010

Jeffrey Shuren, M.D., J.D.  
Director  
Center for Devices and Radiological Health  
CDRH, Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Dr. Shuren:

The National On-site Testing Associates, Inc. (NOTA) represents the manufacturers, users, and distributors of on-site tests to detect illegal drugs. The tests our members manufacture, distribute, and use have a variety of non-medical applications including workplace drug testing. Our tests include urine and oral fluids tests.

The Division of Chemistry and Toxicology Devices in CDRH wants to regulate our on-site oral fluids drug tests that are used in the workplace. They claim these products are "medical devices." However, the statute that determines FDA jurisdiction defines "device" as "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man..." (21 USC 321(h)). According to this law and case law, and past statements by the FDA, the FDA has no jurisdiction unless the device's intended use is for a medical purpose. On-site testing in the workplace is intended for forensic purposes and does not fall under the definition of "device" in 21 USC 321(h).

In 2009, the FDA issued Warning Letters to two of our members. Over the next few months, a discussion ensued with Dr. Harper the Director of the Division of Chemistry and Toxicology Devices. Although we did not concede the jurisdiction issue, we offered to work with FDA to get our products cleared via the 510(k) process. We were asked to use a draft FDA Guidance on drug testing issued in 2003. however, the 2003 draft Guidance applies to urine tests and was not appropriate for oral fluids testing.

On February 26, 2010, we met with the Dr. Harper and Mr. Woods and expressed concern about jurisdiction and the draft 2003 Guidance. As a result of the meeting we believed that the FDA would work with us to develop a guidance, or otherwise provide us with meaningful recommendations, applicable to oral fluids products. Unfortunately, that has not happened. Instead, the FDA has taken the draft 2003 Guidance for urine tests and implemented it with little

consideration of the technical/science differences between oral fluid and urine. We had hoped that the FDA would assist and guide the companies attempting to obtain 510(k) clearance but that does not seem to be happening. There is an apparent unwillingness to assist us through the process.

NOTA was also led to believe that the FDA would grant us adequate time from the February meeting to obtain the 510(k)s. Dr. Harper then imposed an October 2010 deadline on our two members who had Warning Letters. Recently, one of the companies met with Dr. Harper to request an extension of time to obtain the 510(k). Dr. Harper declined the request for an extension, although she acknowledged on a number of occasions during the meeting that there were several problems with the 2003 Guidance. Attached is a memorandum detailing are our concerns about the 2003 Guidance.

We feel that we have reached an impasse. Two of our members are being threatened with an imminent enforcement action in October. We need more time and we need proper assistance on how to obtain the 510(k)s.

We have retained the law firm of Sheppard Mullin in Washington, D.C. to address our jurisdictional concerns with the FDA Office of Chief Counsel. They will be submitting an extensive legal argument to the FDA Chief Counsel next week. We have no desire to be forced into a legal confrontation with the FDA. We are only asking for more time to work with the FDA to develop an effective process.

One of our members will also ask the FDA Ombudsman to intervene regarding the 2003 Guidance and the technical issues.

In light of the legal and technical concerns and especially our willingness to obtain 510(k)s, we respectfully request that we be given the time and the assistance needed and that no enforcement action be taken during this period as long as we act in good faith upon the new recommendations that will be developed.

Sincerely yours,



David G. Evans  
Executive Director

cc: Alberto Guterrez, Ph.D.  
Mr. James Woods  
Courtney C. Harper, Ph.D.

Sent via e-mail and Express Mail

**To: Courtney Harper, Ph.D.**

**From: The National On-site Testing Associates (NOTA)**

**Date: September 30, 2010**

**Re: Concerns about the Draft Guidance For Industry and FDA Staff, Premarket Submission and Labeling Recommendations For Drugs Of Abuse Screening Tests, issued December 2, 2003 and its applicability to oral fluids testing.**

**Introduction - why we are concerned**

We are concerned that the Guidance issued in 2003 for urine tests does not provide proper guidance for the 510k process for oral fluids tests. We want to work cooperatively with the FDA to develop a Guidance for oral fluids tests so that companies seeking a 510k clearance can do so using the best scientific process. The 2003 Guidance is flawed in that it does not address the technical/science differences between drugs of abuse testing in oral fluid versus urine, and the differences between oral fluid instrument-based tests versus point of collection tests.

As a result of the meeting with you last February, we believed that the FDA would work with NOTA and its members to develop guidance that would work for oral fluids. Unfortunately that has not happened. Instead, the FDA has taken the 2003 draft Guidance for urine tests and implemented it without any consideration of the technical/science differences between oral fluid and urine.

We want to make clear to you our concerns about the Guidance.

## PAGE BY PAGE REVIEW OF OUR CONCERNS WITH THE GUIDANCE

### I - INTRODUCTION - PAGE 1

#### GENERAL QUESTIONS ABOUT MARKETS

The first paragraph of the introduction states that the guidance is for in vitro diagnostic devices intended to screen for drugs of abuse. Our position is that testing done in workplaces, schools, and for sports and insurance is not for diagnostic purposes and that application of these guidelines to the proposed markets is outside the authority of the FDA. We are concerned that the FDA may not be fully informed know about these markets and how the tests are used professionally by trained operators. We can inform the FDA as to the following:

1. How consumers are trained in test administration by the manufacturers and distributors.
2. How cost effects use.
3. How workplaces use the tests.
4. The approach used by SAMHSA in their draft regulations in these markets.
5. How laboratories sell to workplaces and how the 2003 FDA Guidance will put us at a disadvantage.
6. How the laws for SAMHSA, CLIA, and the states overlap and that there is redundant legal protection for consumers.
7. The lack of court cases on these tests which indicates that there are no problems with them that have been litigated.

#### CONCERNS WITH THE INTRODUCTION TO THE 2003 GUIDANCE

1. Although the Guidance states that it is for tests using urine, hair, saliva or other matrices, urine is used in the Guidance for examples and it reflects a similarity to 510(k) Prescription Use FDA submission requirements for instrumented, lab-based urine testing products and methods. Consideration should be given to the differing requirements of other technologies and sample matrixes. Has the FDA through the pre-IDE process provided detailed guidelines for testing and getting alternate matrices approved? If so, please provide such detailed guidance.
2. There are significant inconsistencies in these proposed guidelines that conflict with standards that are already applied in certain industries that are already regulated by the US Government such as SAMHSA and DOT or by state laws (drug and alcohol testing in the workplace). There are many state laws that govern workplace testing that include oral fluids testing (see the attached

as examples).

3. The FDA should review the data that shows that inexperienced users can use a specific product with reliable results. Would the FDA consider data that shows that a product gives results similar to a predicate device, and a non-trained user will obtain results similar to a trained professional?

4. Would the FDA consider how the complexity of the products being used would change the oversight requirements in these environments?

5. Will you consider the unintended consequences of significant and undesired effects on drug testing in general by the Guidance by significantly increasing the cost, and decreasing the amount of testing being done?

6. It has been validated many times that testing routinely for drugs is the best deterrent for drug use. We believe that the melding of the FDA's Guidance within the framework of the guidelines that already exist, such as those of SAMHSA and DOT and state law, would do more to further promote public health and safety.

## II. DEVICE DESCRIPTION - PAGE 4

1. Do the product codes listed for the various drugs include all of the currently available and commonly used methods?

## B. GENERAL STUDY CONSIDERATIONS - PAGE 6

1. Table 1 identifies the proposed requirements for each of the types of studies needed for FDA submissions. With a single exception, the proposed requirements for workplace or other professional uses products are identical to laboratory instrument based products. Our products work differently and that is not taken into account.

2. The study design criteria show the lab-based urine sample bias of the 2003 Guidance. For example, it is simple to obtain multiple samples to test numerous times from a single urine sample of greater than 50 ml. - the sample is the same throughout the sample and should give similar results to all tests performed. However, to apply the same standards to an oral fluids sample with a direct test done on the sample, the ability to run numerous tests does not exist. Since each sample is collected separately, each sample is different. Therefore, it is not possible to test the same sample numerous times. This could provide different results when a sample is very near the cutoff, and, more importantly, makes it impossible to use clinical samples for certain types of data collection or precision testing. If you disagree with this, please explain why.

## C. SPECIFIC PERFORMANCE STUDIES - PAGE 8

### Cutoff Characterization - PAGE 8

1. Is the use of threshold cutoff concentrations as identified by SAMHSA appropriate? Shouldn't manufacturers be allowed to determine their own thresholds based on their own clinical data on the performance of the specific product? The FDA should modify this statement to allow for manufacturers to use different cutoffs if their data supports it.

2. The use of benzodiazapines, barbiturates and tricyclic antidepressants examples in the guidance is not appropriate since the Guidance does not address these types of assays.

### Cut-off Validation Study Design - PAGE 8

Is the use of a 25% above and below the cutoff appropriate for all sample types and technologies? Shouldn't the FDA take into consideration these possible variations in cut-off and sample matrix?

### Study Design - PAGE 12

1. The request for significant numbers of clinical sample at or near the cutoff is overly burdensome and onerous. It is not possible to determine in advance the levels of drugs in a sample. The FDA should consider that clinical samples from street or recreational drug users, unlike prescription drugs users who will have a drug level in a narrow therapeutic range, have drug concentrations across the range of the assay. This would require a significant increase in the number of positive clinical samples in order to get a significant number at or near the cutoff.

2. With respect to the sampling and distribution of the clinical study, the types of data that need to be collected will vary significantly depending on the type of specimen, the assay technology, the intended use of the product, the predicate device, and the manufacturers' claims for their product. Shouldn't the structure of field evaluations be dictated by the sample matrix, assay sensitivity, accuracy and precision, as is currently done with most FDA cleared products?

### Stability - PAGE 13

### Studies in the Workplace and Other Sites Performing Repetitive Testing - PAGE 13

1. The proposed user specific data generation and labeling is very problematic because it requires clinical data for each subset of professional use market. The requirement that a manufacturer try to perform expensive, difficult and expensive clinical trials in every single sub-market is overly burdensome and onerous. This is especially true in some markets where the positivity rate is very low and it will take significant numbers of samples to obtain the needed number of positive results. It is better to use one representative site for professional use.

2. It is burdensome and onerous to require that these studies are performed in each environment the product will be used. It is sufficient to provide data that shows inexperienced users can use a specific product with reliable results. Within that context, it should be adequate to show a product gives results similar to a predicate device, and a non-trained user will obtain results similar to a trained professional. The test system should provide both the non-trained user and the professional equal ability to obtain valid test results.

3. The requirement mandating workplace, school, sport, and insurance method comparison and precision studies, in addition to all of the data required by the previous 8 sections of this Guidance, is overly onerous and burdensome and unfair.

#### Home Use Consumer Studies - PAGE 14

##### Study Design

1. It is better for the structure of field evaluations be dictated by the sample matrix, assay sensitivity, accuracy and precision, as is currently done with most FDA cleared products.

2. The requirement in the 2003 Guidance to use pooled, spiked samples for the study design shows the bias toward lab-based urine products.

#### IV. LABELING CONSIDERATIONS - PAGE 16

##### A. GENERAL LABELING FOR DRUGS OF ABUSE SCREENING DEVICES - PAGE 16

##### Intended Use

1. The requirement for a specific setting of use in the labeling is onerous and burdensome because it requires a manufacturer to use user-specific labeling in each market. This is very problematic to implement because manufacturers, distributors, and even some service providers provide these products and services in multiple markets. It is overly burdensome to require the manufacturers, distributors and users to manufacture, distribute and use a different product for each of these slightly different submarkets of the professional use category. These users are trained by the manufacturers and they have similar levels of training and skills. The FDA does not need to require such specific labeling to ensure proper use.

2. Is the suggested labeling identifying the minimum numbers of tests performed by an operator per week appropriate? Most of these products very simple to use and even when used occasionally, will generate an accurate result. The tests are so operator-independent that it is almost irrelevant who performs the test. The FDA needs to consider how the complexity of the products being used would change the oversight requirements in these environments.

3. A confirmation test should only be required when a confirmation would be required for the lab-based method. A confirmation test should be recommended on positive results only as is currently the practice in laboratory and professional use markets such as the workplace, schools, sports and insurance testing.

4. Is the requirement that a confirmation test be done by GC/MS always appropriate? Shouldn't the use of a different method to confirm the initial result be sufficient? This is current practice for many tests done either inside or outside of a laboratory environment. For example, alcohol testing is normally done under DOT requirements and under state law for forensic use. In both situations, a second test is often considered a confirmation test. This approach has been validated by the courts.

5. The proposed labeling guidelines are more stringent than the current requirements for a Prescription Use 510(k) product used in a laboratory by trained personnel. The proposed requirement to include all of the proposed information in labeling for the professional repetitive use markets such as the workplace, schools, sports and insurance use markets is unnecessary and is likely to lead to more confusion by the user. A more focused presentation of the important information in a simple and easy to use format will be much more likely to be understood.

#### Summary and Explanation of the Test - PAGE 17

1. Why is there a recommendation to restrict FDA clearance of products meeting SAMHSA cutoffs when the SAMHSA cut-offs only apply to government testing in the federally regulated workplace and to urine? As with all other FDA cleared products, the recommended cutoffs for each product should be established and validated by the manufacturer of the product and then the final cutoff selected by the user, based on the use of the product. With drugs of abuse testing, the cutoffs selected will vary significant depending on the use of the product. The SAMHSA guidelines may be appropriate for SAMHSA regulated markets only, and should not be automatically used by FDA.

2. Is the provision of pharmacokinetic data appropriate or useful for screening assays? Since most of the data found in the literature cites GC/MS results on samples obtained from single dose studies, it would be better that such data not be included because the clearance rates are the result of multifactorial influences including, level of drug dose, method of drug delivery, metabolic rate of subject and the sensitivity of the assay system used for drug detection. The inclusion of such data will not only be misleading, but, under some circumstances, incorrect.

#### Understanding the Test Result - PAGE 17

1. The suggested wording in the proposed guidance shows a lab bias that on-site products give marginal performance. This belief is not consistent with data generated in FDA submissions for some of the products. Is it the FDA's policy to advantage one type of product over another when the science shows that they perform equally as well?

2. Aren't the data and the suggested wording for labeling specific to on-site urine products only and do not apply to other specimen types? The labeling should reflect the performance of the product being used and not general statements. Shouldn't consideration be given to why a product might give a false positive or negative result such as the use of over-the-counter medications, etc.

3. Is the requirement for extensive labeling on false positive and false negative results necessary?

#### Quality Control - PAGE 19

1. The requirement to evaluate QC materials with drug concentrations in the samples at 25% above and 25% below the cutoffs is not appropriate. It does not show recognition of technology or sample matrix differences.

#### Limitations - PAGE 19

1. It is burdensome and onerous to require manufacturers to specifically identify those markets that the product has not been labeled for in the professional repetitive use markets. Won't a manufacturer only be able to make claims in those markets in which extensive and duplicative, therefore unnecessary, studies have been completed and data provided? Don't these users have similar levels of training and skills and, therefore, should the FDA require such specific user specific clinical trials and labeling to ensure proper use? Shouldn't labeling, but also the clinical trials, be for all repetitive use workplace type settings such as sports, schools, and insurance testing?

2. It will be very confusing to have multiple labeling in a single product even if it can be accomplished. This will become very problematic to implement when manufacturers, distributors, and even some service providers provide these products and services in multiple markets. It is overly burdensome and onerous to require the manufacture, distribution and users to manufacture, distribute and use a different product for each of these slightly different submarkets of the professional use category.

#### Performance Characteristics - PAGE 20

##### Cut-off Characterization and Analytical Sensitivity

1. Is the requirement to include all of the proposed data appropriate for all but the laboratory testing market? Including operator specific data is onerous and unnecessary. This information should be included in the submission but not the labeling.

Comparison to predicate or reference methods

1. Is the requirement to include all of the proposed data not appropriate for all but the laboratory testing market?

## B. SPECIAL CONSIDERATION FOR LABELING FOR HOME USE DEVICES

Overview

1. The statement “laboratory test is more accurate” is not completely true and is misleading. Some on-site test methods are actually more accurate than some methods that are used in laboratories.
2. The proposed example shows a bias toward lab-based urine tests. The confirmation test may not confirm the initial result, not because the initial result is incorrect, but because the second sample is probably collected at a different time. Wouldn't it be better rather than trying to explain where and how to get a confirmatory test, to recommend that a statement to consult with a healthcare professional be used rather than a mandatory confirmation test?

## C. SPECIAL CONSIDERATIONS FOR LABELING OF WORKPLACE AND OTHER REPETITIVE SITE TESTING - PAGE 24

1. Isn't it true that with one exception, the proposed requirements for workplace or other professional uses products are identical to laboratory use products (see previous questions)?
2. It is overly burdensome and onerous to require the manufacturers, distributors and users to manufacture, distribute and use a different product for each of these slightly different submarkets of the professional use category.

## D. OUTER BOX LABELING - PAGE 25

For devices Intended for Laboratories and Workplace Settings

1. Is the proposed requirement to indicate that any result, positive or negative, is presumptive only, appropriate? Shouldn't a confirmation test be recommended on positive results only as is currently the practice in laboratory and professional use markets such as the workplace, schools, sports and insurance testing?

## OTHER CONCERNS

1. Does the FDA have proof that there is a problem with the broad range of these tests? Have there been complaints, court cases or other indicators of problems? If so, please provide this information. We have made previous requests for such information.

2. If the FDA requires approval under the 2003 Guidance, the costs of approval will include the testing, FDA submissions and approvals, as well as changes in labeling costs. This cost will have to either be forwarded to the customer or absorbed by the company thereby decreasing the profit margins. This will cause an increased strain on American manufacturers and distributors of on-site drug testing products. Although many small companies have initiated a drug testing policy, our research shows that often they do not enforce the policies due to the high cost of each test required to send to the lab. The average cost for testing and the time required to send the person to the laboratory collection site and the interruption in work flow costs the company between \$100 and \$300 per person, each time. For a small business in lean times this is too costly.

There are indirect costs as well. There will be an inevitable increase in drug use within the companies who are not doing drug testing that will result in increased absenteeism, decreased productivity, and higher turnover which then translates to higher training costs, more mistakes by the new people and decreased morale by those who are 'towing the line'.

An on-site drug testing program that is effectively and continually implemented, enables workers to focus on their job and keeps all of them on a 'level playing field'.

3. Does the FDA intend to assert jurisdiction over this technology whose use poses no health risks?

4. There may be a need to set guidelines for OTC products in environments where there are casual, infrequent users, such as in home use, but the application of these same guidelines to the more routine, professional use in the workplace, sports and insurance is not appropriate.

5. The FDA justifies the inconsistency in its regulation of workplace testing and not testing in the criminal justice system by claiming that people who are tested by the criminal justice system have access to lawyers and the courts. This is also true with workplace testing. For example, union members have access to union attorneys. There are hundreds of court cases and many state laws on employment drug testing (see the attached as examples). Obviously, employees have access to the legal system and in many cases better access as they have jobs and can retain an attorney. There are great financial incentives. Some cases where testing was done improperly have resulted in large awards for employees.

# Drug Testing Law, Technology and Practice

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By  
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*Pittstown, New Jersey*

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## DRUG TESTING LAW, TECHNOLOGY AND PRACTICE

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