ALCOPRO
DRUG AND ALCOHOL TESTING PRODUCTS

Comments Regarding

Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications, November 14, 2000
Docket No. 99D-1020

About AlcoPro, Inc.

AlcoPro, Inc. has been in business for 18 years supplying on-site drug testing kits and alcohol testing devices to a wide variety of users throughout the country. AlcoPro supplies a variety of customers, including drug and alcohol treatment programs; correctional programs such as probation and parole agencies, work release programs, and jails; workplace; and schools. AlcoPro, Inc. distributes on-site drug testing devices from several manufactures. We distribute five types of on-site alcohol testing devices, and also manufacture our own on-site breath alcohol testing device.

AlcoPro, Inc. is one of many companies who have strictly followed FDA guidance by refusing to sell on-site drug testing kits to consumers unless that device has received FDA OTC clearance. We make this point to distinguish ourselves from those companies who have blatantly ignored FDA guidance regarding this issue, and who continue to blatantly ignore FDA guidance regarding this issue.

Comments:

Our comments relate to three areas:
1. We disagree with the application of OTC guidance to non-professional use settings of workplace, insurance, and sports.
2. We disagree with the requirement to include confirmation testing with every OTC drug screening device.
3. We disagree with the suggestion to include OTC guidance to alcohol screening devices.

1. FDA has no jurisdiction over the use of on-site drug testing kits in the workplace, criminal justice, athletics, insurance, schools, and any other non-diagnostic testing use.

By regulatory authority, FDA has jurisdiction over diagnostic products. When on-site drug testing kits are used in the workplace, criminal justice, athletics, insurance, schools, and other similar settings, no diagnosis is performed. Drug testing in these arenas is usually performed for "program compliance," that is, to determine if that individual is following rules or regulations. There is no medical decision being made, and certainly no diagnosis.

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Is the FDA perhaps making the assumption that if any individual has drugs in their system, that individual is, on that fact alone, medically diagnosed as a "substance abuser?" And therefore, any such determination by on on-site drug screen that drugs may be present in a person's system is a diagnostic test - regardless of who performs the test? If this is indeed the logic implied by FDA, we cannot agree. Neither do we think any professional engaged in the treatment of substance abusers will agree that a "substance abuser" can be diagnosed by a single drug test which shows the presence of drugs in that person's system.

2. We disagree with the requirement to include confirmation testing with every OTC drug screening device.

The only stated reasons for applying OTC guidance to workplace, insurance, and sports settings are "concerns about sample integrity and test accuracy." These are honorably objectives. We believe the on-site drug testing industry shares the same concerns, and already adequately addresses these issues. We do not believe that the guidance does much to improve sample integrity. And we believe the market already provides accurate on-site screening devices, and already provides adequate mechanisms for confirming on-site screening results.

Having been in the drug and alcohol industry for 18 years, we have seen a bias against on-site drug testing kits from certain professionals who have spent their careers in laboratories. Such a bias is understandable from a business point of view; on-site drug testing kits likely do have a financial impact on some laboratories. It is understandable that any business will do what they can to protect and enhance their financial well being. The proposed requirement to include a GC/MS confirmation test benefits laboratories, without a doubt. Our guess is that the thinking behind applying OTC guidance to the arenas under discussion comes from people who have spent their careers in laboratories, or are closely affiliated with laboratories. Such laboratory professionals may tend to think that the highest degree of accuracy obtainable with a GC/MS test should be used for every non-negative drug test.

We believe the user of an on-site drug screen should be fully informed about the accuracy of the on-site test, and the accuracy of GC/MS confirmation. We also believe the user should be allowed to choose whether to have a specimen confirmed with GC/MS. We believe it is up to the consumer to choose the degree of accuracy they require for their situation, balanced against how they will use the information and the cost of the GC/MS confirmation.

There are other on-site screening devices on the market, such as pregnancy testing kits, for which the FDA does not require confirmation on non-negative results. Consumers of *pregnancy* kits are not required to also purchase a laboratory test to confirm the result of the screen. We fail to understand why the FDA proposes to require consumers of on-site *drug* testing kits to also purchase a laboratory test to confirm the result of the screen. We

disagree with the FDA proposal to require every user of an on-site drug testing device to also purchase the most expensive option of GC/MS confirmation with every device.

3. We disagree with the suggestion to include OTC guidance to alcohol screening devices.

Our objections are so many, we barely know where to begin in describing our objections to the FDA proposal to include OTC guidance to alcohol testing. More so, we are at a loss to comprehend why FDA even suggests applying FDA OTC guidance to alcohol screening devices. For over 30 years many users in every arena have satisfactorily met the alcohol testing needs by using alcohol screening devices. To apply OTC guidance to these devices would greatly increase the cost of those that chose to meet FDA OTC guidance, thereby significantly reducing the use of these devices. The idea of applying OTC guidance to alcohol testing devices is so unwieldy, we wonder if the decision makers at FDA have any idea of how widespread is the use of these devices, and how successfully they meet the users needs.

Alcohol screening devices have been sold without FDA involvement for over 30 years. Over the years the FDA has explicitly told our company, and other manufacturers of alcohol testing devices, that these devices were not under FDA jurisdiction. The devices are sold to every imaginable market segment: workplace, corrections, law enforcement, drug and alcohol treatment programs, schools. These programs are aware of the capabilities and limitations of these devices. The devices play a vital role in these programs as a deterrence to alcohol use, and in detecting alcohol use.

Most discussions about substance abuse lump will describe alcohol as a drug, along with drugs of abuse such as marijuana, cocaine, heroin, etc. However, alcohol is significantly different from other drugs of abuse in that alcohol is not illegal. We have previously discussed how detecting the presence of a drug of abuse, in itself, cannot classify an individual as a "substance abuser." It is an even bigger stretch of logic to say that detecting the presence of alcohol in an individual classifies that individual as an "alcoholic" or "substance abuser," and that therefore, the device used to detect that alcohol must be a diagnostic device.

Nonsense! The FDA clearly has no jurisdiction over the use of alcohol testing devices when they are not used as a diagnostic device. When an on-site alcohol test is used to determine if a person has had anything to drink or not (i.e., a teenager at high school) or how intoxicated an individual is (i.e.., an adult drinking at home), no diagnosis is performed.

FDA "seeks input on what testing, if any, should be used for confirming presumptive positive screening tests for alcohol." The same issues discussed earlier regarding the consumer's right to choose the device appropriate for their need - balancing the appropriate degree of accuracy with the appropriate cost - apply to alcohol testing as well.

In addition to our assertion that the user be allowed to choose to confirm the result of a screen, the very logistics of confirming alcohol screening tests are problematic. The only confirmation methods we would recommend for alcohol screening tests are blood alcohol tests, and Evidential Breath Testers (EBT). Both methods are expensive. Both methods are not readily or conveniently available to the majority of alcohol screening device users. Because alcohol levels decline so rapidly, a delay of even an hour in performing a confirmation test may be too long to meet the user's need. Blood alcohol tests are invasive. Blood alcohol results are not immediately available.

Perhaps the difficulty here is that FDA is attempting to impose a laboratory type testing scheme upon all users, and the laboratory testing scheme doesn't fit. Our experience is that those programs who truly value confirmation of alcohol screening tests, do confirmation testing now. These are programs who have decided they need that high degree of accuracy in results, and are willing to pay for the blood alcohol test or EBT confirmation tests. Other users who do not need that highest level of accuracy for the decisions they will make, choose not to confirm alcohol screens. Given that there is little perceived problem with the status quo of alcohol testing, trying to impose a very problematic and unwieldy confirmation scheme on all users doesn't add up.

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