#04-7984
P.C. 8400112

5600 Fishers Lane
Rockwall II
Suite 815
Rockville
Maryland 20857

12th July 2004

Dear Sir or Madam

RE: SAMHSA Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs (Docket # 04-7984)

I write with reference to the above document and would like to make the following comments for consideration on behalf of Cozart Bioscience Ltd.

1. **Section 8.3** details the proposed procedure for collection of an oral fluid sample through spitting directly into a specimen tube under direct supervision.

This proposed procedure does not permit provision for the use of FDA approved drugs of abuse oral fluid collection devices that have shown not to affect the specimen in an adverse manner. Of equal importance is that the device needs to collect a specified volume of oral fluid. As noted on page 19680 of the document, a known volume of oral fluid is required to establish specific cut-offs for oral fluid testing. With the current state of testing technology, a 1mL volume of collected, neat oral fluid should be sufficient for screening and confirmation testing.

We propose that the guidelines are amended to include suitable FDA approved oral fluid collection devices that collect defined volumes of oral fluid specimens for drug testing. The volume collected should be reproducible (within 20% of the target volume) with target volumes between 1 and 2 mL. We would also propose that provision for splitting the sample be made an option to be carried out at the laboratory or at the site of collection.

2. **Section 3.9** details the proposed procedure for validity tests to be

carried out on all oral fluid specimens.

The use of a device with a sample adequacy (volume) indicator as described above will also ensure that a sufficient volume of oral fluid is collected. When used under direct supervision and under full chain of custody, this would negate the need for the requirement of validity tests for substitution.

3. **Section 2.2(a)** proposes that a urine specimen should be collected whenever an oral fluid specimen is collected.

This proposed regulation eliminates the advantages that oral fluid collection brings to Federal Workplace Testing and in addition will result in increasing the cost of the testing procedure and time required for testing. We propose that the guidelines are amended to collect only one specimen unless there is difficulty with the collection (shy bladder, dry mouth) as detailed in section 2.2(b). This could be further augmented by the use of a hair sample as a better alternative to urine. A hair sample could be collected weeks after the initial test and also provide a longer window of detection.

We see the introduction of alternate testing as a positive step as we have been involved in oral fluid testing in the U.K. for a number of years. In our experience the levels of drugs found in real life are much higher than those seen in research situations and therefore windows of detection are likely to be longer.

If you need any further information please do not hesitate to contact me.

Yours sincerely

Dr Gail Cooper BSc (Hon.), MSc, PhD
Head of Analytical Services Division/Forensic Toxicologist

From: "Gail Cooper" <cooper@cozart.co.uk>
To: <wvogl@samhsa.gov>
Date: 7/12/04 9:40AM
Subject: Docket # 04 - 7984

Please find attached our comments on the Proposed Revision to the Federal Workplace Guidelines (Docket # 04-7984).

Yours sincerely

Dr Gail Cooper

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CC: "dene" <dene@cozart.co.uk>, "Chris Hand" <chris@cozart.co.uk>

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