



Laboratory Corporation of America® Holdings
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Burlington, North Carolina 27215

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Telephone: 336-584-5171

Re: Draft Guidance for Industry and FDA Staff; Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests [Docket No. 2003D-0522]

Dear Sir or Madam:

The following comments are being offered by Laboratory Corporation of America Holdings (“LabCorp”) in response to the above-captioned draft guidance (the “Guidance”), notice of which was published in the *Federal Register* on Tuesday, December 2, 2003 at 68 Fed. Reg. 67460.

With six SAMHSA-certified laboratories throughout the United States, LabCorp is one of the largest occupational substance abuse testing providers in the world. In addition to substance abuse testing, LabCorp offers on-site screening for drugs of abuse with confirmatory testing for presumptive positive drug screen results. LabCorp is therefore affected by this Guidance.

The practical effect of this Guidance is likely to be a significant reduction in utilization of gas chromatography / mass spectrometry (GC/MS) confirmation of presumptive positive drug screening results. Since false positive drug screening results have significant adverse effects on prospective and current employees, employers, and others for whom such screening is administered, and since screening tests are generally only useful for making a preliminary determination as to whether or not a particular drug or class of drug is present, confirmation of such preliminary presumptive positive results by an accurate and reliable method such as GC/MS is essential.

The FDA’s previous draft guidance issued on November 14, 2000, entitled “Over the Counter (OTC) Screening Tests for Drugs of Abuse: Guidance for Premarket Notifications”, appropriately recognized the importance of confirmation testing by recommending that the information in the package insert include a clear statement indicating that confirmatory testing will be conducted on all samples that initially test positive. At the meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel held on November 13, 2000, Dr. Jean M. Cooper, Branch Chief, Clinical Chemistry and Clinical Toxicology Branch, Division of Clinical Laboratory Devices, said in reference to that draft guidance that the FDA intended to require the cost of confirmation to be included in the price of the device.¹ Panelists at the meeting agreed that confirmation testing was essential, and concurred that the cost of confirmatory tests could be

¹ Summary Minutes, Meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel, Open Session, November 13-14, 2000, pp. 6-7.

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offset by the price of the initial test.² FDA representative Dr. Steven I. Gutman indicated that the intention is to catch false positives, and that by building the cost of confirmation testing into the price, the FDA hopes to encourage the practice.³

In the Guidance, the FDA's previously stated intention that the cost of confirmatory testing be bundled with the cost of screening tests has been replaced by recommendations for cautionary labeling and other controls to address concerns over possible inaccurate preliminary results. The FDA states in the Guidance that it recognizes that the risk of inaccurate or unreliable results in a repetitive-use environment like the workplace may be addressed in ways other than bundling a proportionate cost of confirmatory testing into the costs of screening tests, and that labeling and other performance controls may help mitigate the risk of inaccurate or unreliable results, and may do so at less cost to the manufacturer and consumer.

Whether the Guidance will mitigate the risk of inaccurate or unreliable results and do so at less cost remains to be seen; the FDA appropriately uses the word "may" to characterize the positive effects of the Guidance as a mere possibility, and offers no support for this change in policy other than the fact that the previous draft guidance elicited concerns from some because of the recommendation to bundle the cost of screening with the cost of confirmatory testing. We submit that the Guidance is far less likely to mitigate the risk of inaccurate or unreliable results or do so at less cost than requiring a proportionate cost of confirmation to be included in the price of the screening device.

Cautionary labeling is not a viable substitute for GC/MS confirmation of presumptive positive drug screen results. GC/MS has been the recognized benchmark for accuracy in forensic toxicology for more than three decades. Labels are not always read, understood, or followed by end users, but bundling the cost of confirmatory testing with the cost of a screening device creates an economic incentive for end users to obtain confirmation of presumptive positive drug screens – a result that should be encouraged, not left to chance. We further submit that the short term, negligible cost savings, if any, achieved by permitting marketing of drug screen devices without bundling a proportionate cost for confirmation testing will be significantly outweighed by the societal costs associated with the unconfirmed, presumptive positive drug screen results that the Guidance is likely to encourage.

LabCorp appreciates the opportunity to provide comments on this Guidance and urges the FDA to reconsider its position on this issue. If you have any questions concerning these comments, please contact me at (336) 436-5040.

² *Id.* at pp. 8-9.

³ *Id.* at p. 9.

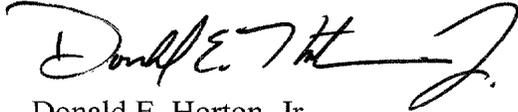
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Very truly yours,

LABORATORY CORPORATION OF AMERICA HOLDINGS

A handwritten signature in black ink, appearing to read "Donald E. Horton, Jr.", written in a cursive style.

Donald E. Horton, Jr.
Director, Public Policy

FDA Letter 040604

Cc: Dave King
Bradford Smith
Randy Simmons
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