ABBOTT LABORATORIES

Corporate Regulatory and Quality Science 3668 '03 DEC -1 A8:52

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

RE: *Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use; Draft Guidance for Industry and FDA Staff [Docket 2003D-0383]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use," published in the Federal Register on October 28, 2003 at 68 FR 61449.

Thank you for the opportunity to provide these comments. FDA's guidance on the use of symbols for professional use *in vitro* diagnostic devices (IVDs) and adoption of the guidance by both CDRH and CBER is welcomed.

Our comments pertain to section VII of the guidance document, "Glossary of Terms." As stated, the purpose of the glossary is to allow users to become familiar with the symbols and to act as a reference tool. In this section, "FDA encourages the inclusion of the glossary in the package insert." We recommend recognition, in the guidance document, of alternative mechanisms to provide such information for several reasons. First, it is important that manufacturers have the flexibility to supply the glossary in the most useful means to the customer. Second, professional laboratories purchase multiple IVDs and will receive multiple glossaries from various sources. Third, as professional laboratories become more accustomed to the symbols, the need to provide multiple glossaries will diminish.

Inclusion of the glossary as a separate labeling piece with IVD reagents may be more suitable than revising multiple product package inserts to include the glossary. Alternatively, a glossary included as part of an instrument operations manual would serve as a reference tool for the laboratories using reagents that are part of that same instrument system. Reference cards are another means to convey the information. In

2003D-0383 C4

situations, were calibrators and controls are part of an IVD system, inclusion of the glossary as part of the instrument operations manual or IVD reagents may be appropriate.

FDA's recognition of alternative mechanisms to provide the glossary of terms will provide manufacturers with the flexibility to respond to the level of information needed by the market place. Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-3106.

Sincerely,

April Veoukas

April Veoukas, J.D.
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