Promega

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November 4, 2003

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

RE: Docket No. 2003D-0383

Dear Madam/Sir:

The *Draft Guidance for Industry and FDA Staff Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use* is a significant step towards enabling industry to eliminate the need to maintain dual inventories of products; one labeled per U.S. regulations and the other labeled per EU standards. The capability to supply products to the U.S. and Europe that conform to one set of labeling requirements will lead to significant cost savings for industry.

Given that the guidance document specifically addresses IVDs for Professional Use, please consider an alternative to the following label statement requirements specified in 21 CFR 809.10. Per 21 809.10(d)(1)(iv), the labels for general purpose reagents (864.4010) are required to include the statement "For Laboratory Use" and per 809.10(e)(x)&(xi), the labels for analyte specific reagents (864.4020) are required to specify either "Analyte Specific Reagent. Analytical and performance characteristics are not established" or "Analyte Specific Reagent. Except as a component of the approved/cleared test (Name of approved/cleared test), analytical and performance characteristics of the ASR are not established."

Since a professional user could in no way confuse a GPR or ASR with a finished IVD system or kit, it seems reasonable to allow the use of the **IVD** symbol and/or the statement "For In Vitro Diagnostic Use" for both GPRs and ASRs. Within the EU, GPR and ASR reagents would be defined as IVD Accessories. Directive 98/79/EC on *in vitro* diagnostic medical devices defines an IVD accessory as "an article which, whilst not being an *in vitro* diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose".

Additionally, per Directive 98/79/EC *Article 1*, Paragraph 1, "This Directive shall apply to *in vitro* diagnostic medical devices and their accessories. For the purpose of this Directive, accessories shall be treated as *in vitro* diagnostic medical devices in their own right. Both *in vitro* diagnostic medical devices and accessories shall hereinafter be termed devices."

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The label requirements specified in ISO 15223 and EN 980 apply equally to *in vitro* diagnostic medical devices and IVD accessories.

Thank you for your consideration of this request.

Sincerely yours,

Joseph E. Schwarz MS, MBA, RAC
Regulatory & Quality System Compliance Manager
Regulatory Affairs & Quality System Engineering

CC: Terri Garvin, OIVD, CDRH, FDA