DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

DADE BEHRING

Nov. 24, 2003

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

Re: FDA Docket No. 2003D-0383: Draft Guidance for Industry and FDA Staff; Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use; Availability

Dade Behring Inc, a manufacturer of in vitro diagnostic devices, respectfully submits comments to the Draft Guidance: Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use. The availability of the guidance document was announced in the Federal Register Vol. 68, No. 208, Oct. 28, 2003.

Dade Behring appreciates FDA's efforts to develop this draft guidance, which provides their preliminary thinking on this topic. We support the use of symbols in labeling for the following reasons:

- Harmonizes with efforts of international standards-making bodies.
- Provides a mechanism for conveying the required information to the end user while acknowledging the space restrictions of labels for in vitro diagnostic devices.
- Promotes less crowded and more legible IVD labels, thus increasing the likelihood that the end user will comprehend the information.

Our comments are provided in Attachment 1. Dade Behring appreciates this opportunity to provide comments and hopes that you find these comments constructive. We look forward to the issuance of this draft guidance in its final form.

If you have questions, please do not hesitate to contact me at 302-631-7626 or by email: lewisyt@dadebehring.com

Sincerely,

Yuk-Ting Lewis

Yuk-Ting Lewis
Regulatory Affairs and Compliance Manager

Attachment 1: Dade Behring's comments to Draft Guidance for Industry and FDA Staff; Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

Reference in guidance doc	Comment and Proposed re-wording	Draft guidance document
p. 7 Sec III	***Comment:*** In addition to the recognized application for the "Consult Instructions for Use" symbol, when space is limited, FDA should permit the use of this symbol in lieu of the intended use statement and list of reactive ingredients, as required by 809.10(a)(2) and 809.10(a)(3). Although the use of symbols increases the space available for text, a product can have a lengthy intended use or reactive ingredients. ***Proposed re-wording:*** As a matter of enforcement discretion, FDA does not intend to object to the use of: • The "Instructions for Use" symbol in place of the intended use statement or list of reactive ingredients. • The "IVD" in a box …	***Current wording:*** As a matter of enforcement discretion, FDA does not intend to object to the use of: • The "IVD" in a box symbol …
p. 8 Sec. IV	***Comment***: FDA has recognized all symbols in ISO 15223 and EN980 (68FR 22391 and 61448). There are 4 symbols that are included in ISO 15223 which are not recognized in the draft guidance. These are the symbols representing: • Fragile, handle with care • Keep away from sunlight • Protect from heat and radioactive sources • Keep dry These symbols could apply to IVDs and therefore, to promote consistency and eliminate possible confusion, they should not be excluded from this guidance. These symbols should also be included in the Glossary of Terms. ***Proposed re-wording:*** FDA recognizes all of the symbols for IVD devices for professional use …	***Current wording:*** FDA recognizes 25 symbols for IVD devices for professional use from the following two international consensus standards: • ISO 15223 • EN980 The following chart displays the symbols with their definitions.
p. 11 Sec. VIII	***Comment:*** We believe no additional educational outreach is needed for the symbols contained within the draft guidance document. A user comprehension study was conducted showing acceptance of these symbols and an explanation is provided in the glossary. We believe that this guidance should be expanded to include a provision for use of symbols in addition to those included in the consensus standards. The requirement for educational outreach should apply to these additional symbols, as well as the requirement for inclusion of the symbol and its meaning in the Glossary of Terms. ***Proposed re-wording:*** When a manufacturer chooses to	***Current wording:*** FDA recommends that manufacturers conduct an educational outreach effort for the intended audience to enhance the understanding of newly introduced symbols. The educational outreach should target the various professional users of IVDs (e.g., laboratory technologists, nurses, laboratory assistants, medical assistants). FDA recommends the following possible methods for

Reference in guidance doc	Comment and Proposed re-wording	Draft guidance document
	utilize a symbol that is not included in ISO 15223 or EN980, FDA recommends that the manufacturer conduct an educational outreach effort for the intended audience to enhance the understanding of the newly introduced symbol. … FDA recommends the following possible methods for education: • print materials such as glossaries (see section VII), wall charts, articles in the laboratory press	education: • print materials such as glossaries, wall charts, articles in the laboratory press