



Corporate Regulatory and Quality Science

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

RE: *Global Harmonization Task Force, Study Groups 1 and 2; New Proposed Documents –“Labelling (sic) for Medical Devices (revised);” SG1(PD)/N043R6 [Docket 2004D-0352]*

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding the Global Harmonization Task Force (GHTF) document “Labelling (sic) for Medical Devices (revised);” SG1(PD)/N043R6 published in the Federal Register on August 23, 2004 at 69 FR 51853.

Thank you for the opportunity to provide these comments. Our comments are presented by section of the guidance document.

Section 4.0 Definitions

We recommend modifying the definition of “performance evaluation” by replacing “review of the performance” with “an investigation.” When read in context of section 5.2 (n) of the document the term is intended to reflect an investigational study of an *in vitro* diagnostic device (IVD), similar to a clinical investigation of a medical device, rather than a review of the data collected during the investigation.

Section 5.1 General Principles

Bullet point six

To clarify that labeling may be provided by only one of the listed means we recommend inserting “any of” prior to “several means,” so the sentence begins “Labelling (sic) may be provided to the user in various media and by any of several means...”

Bullet point nine

We recommend including additional guidance to assist in determining when a “newly introduced symbol” becomes an established symbol. For example, adoption of principles developed by ISO TC 210 WG 3 on the validation of symbols or approved

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methods to validate the effectiveness of symbols developed for non-medical device products, such as the European Telecommunications Standards Institute (ETSI), "Human Factors (HF); The Multiple Index Approach (MIA) for the evaluation of pictograms," F.910 ITU "Procedures for designing, evaluating and selecting symbols, pictograms and icons" (also ETSI ETR 070, "The Multiple Index Approach MIA for the evaluation of pictograms"), and ISO 9186 "Graphical Symbols -- Test methods for judged comprehensibility and for comprehension."

Section 5.2 Content of Labeling

Subsection 5.2(a)

To minimize country-specific labeling requirements we recommend modifying the statement regarding requiring the name and address of the importer or authorized representative for imported devices to read:

For imported devices, should a country/region request labeling containing the name and address of either the importer established within the importing country/region or of an authorized representative of the manufacturer established within the importing country/region it should request this information in a manner that is consistent with minimizing country-specific labeling requirements. For example, when paper labeling contains the name and address of the manufacturer it may include an internet address that lists the name and address of the importer or authorized representative by country.

Subsection 5.2(c)

The expectation regarding lot or serial number pertaining to "detachable components" in terms of IVD instruments is unclear, and may result in incongruent application or unintended broad interpretations. We recommend clarifying that "detachable components" refers to components intended by the manufacturer for detachment by the user, so the end of the sentence reads, "and any intended user detachable components."

Subsection 5.2(n)

This section permits alternative labeling for investigational devices or IVDs. However, it does not provide an exemption from labeling requirements that may not be available due to the investigational nature of the device or IVD, such as performance characteristics. We recommend adding an exemption, such as "thereby alleviating compliance with requirements of this document that are not available due to the investigational nature of the device or IVD."

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,



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