



November 18, 2004

Via fax and UPS

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

Re: Docket No. 2004D-0352

Global Harmonization Task Force, Study Groups 1 and 2; New Proposed Documents

- (1) *SG1(PD)/N043R6: "Labelling for Medical Devices (revised)" - GHTF Study Group 1*
- (2) *SG2(PD)/N38R14: "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program" - GHTF Study Group 2*

[Federal Register/ Volume 69, No. 162, pages 51853-51854]

Dear Sir/Madam:

Aventis appreciates the opportunity to comment on the above-referenced docket with respect to the proposed Global Harmonization Task Force (GHTF) Study Group documents.

GHTF Study Group 1 document SG1(PD)/N043R6, "*Labelling for Medical Devices (revised)*," is intended to describe revised harmonized requirements for the labeling of medical devices.

GHTF Study Group 2 document SG2(PD)/N38R14, "*Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program*," is intended to provide information to authorized representatives on the prerequisites and commitments required of an organization before they can participate in the National Competent Authority Report (NCAR) exchange program.

We offer the following comments and questions for your consideration.

2004D-0352

C1

**GHTF Study Group Document SGI(PD)/N043R6: Labelling for Medical Devices
(revised)**

4.0 DEFINITIONS

Instructions for use: Information provided by the manufacturer to inform the device user of the products (sic) proper use and of any precautions to be taken.

Recommendation: Aventis suggests emphasizing that Instructions for Use are considered labeling, by changing the definition from "Information provided by the manufacturer..." to "Labelling that provides information from the manufacturer...." Please also note a typographical error in the text: "products" should have an apostrophe: "product's."

5.0 LABELLING REQUIREMENTS

5.1 General Principles

4th bullet:

- *Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.*

Recommendation: Aventis suggests adding: "Readability testing of the instructions may be appropriate, particularly for complex devices." Readability testing would contribute to the shared goal of reducing medication errors by enhancing document comprehension.

5.0 LABELLING REQUIREMENTS

5.1 General Principles

5th bullet:

- *Instructions may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the manufacturer without any such instructions.*

Recommendation: Aventis suggests changing this to read: "Instructions may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the manufacturer without detailed instructions." All devices, no matter how simple, should have some instructions for use. Aventis also suggests providing examples of such low- or moderate-risk devices.

5.0 LABELLING REQUIREMENTS

5.1 General Principles

8th (next-to-last) bullet:

- *Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum.*

Recommendation: Aventis requests further explanation. Should Regulatory Authorities aim to waive or eliminate national language requirements if the intended users (e.g., physicians or other healthcare providers) are presumed to be multilingual by virtue of their education and professional training?

5.0 LABELLING REQUIREMENTS

5.1 General Principles

First paragraph after the bullets:

Regulatory Authorities and Industry should encourage the development and use of international labeling guidelines for medical devices.

Recommendation: Aventis recommends extending this principle also to the standardization of symbols, changing the sentence to read: "*Regulatory Authorities and industry should encourage the development and use of international labeling guidelines and standardised symbols for medical devices.*"

5.0 LABELLING REQUIREMENTS

5.2 Content of Labelling

a) *The name or trade name and address of the manufacturer...*

For imported devices, information may be required to contain in addition, 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 county/region.

Recommendation: Does "name or trade name" pertain to the product or the manufacturer? Both should be included. Aventis proposes changing the first sentence to read: "*a) The product name or trade name, the manufacturer's name and address,*"

5.0 LABELLING REQUIREMENTS

5.2 Content of Labelling

b) Sufficient details for the user to identify the device and, where these are not obvious, its intended purposes, user and patient population of the device; also, where relevant, the contents of any packaging.

Recommendation: Aventis suggests deleting the words "where relevant." This is important information and should not be optional.

5.0 LABELLING REQUIREMENTS

5.2 Content of Labelling

h) The performance intended by the manufacturer and, where relevant, any undesirable side effects.

Recommendation: Aventis suggests replacing the term "undesirable side effects" with the preferred term "adverse events." GHTF documents generally use the term "adverse event." "Side effects" is a term regulators have been trying to eliminate.

GHTF Study Group 2 document SG2(PD)/N38R14, "Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program"

3.0 DEFINITIONS

Confidential Information: Information that due to its nature may be unfairly prejudicial to one or more persons and that, for this reason, has been marked by the information provider as being confidential or not for general release.

Recommendation: Aventis suggests adding the words "or participants," such that the definition reads: "*Confidential Information: Information that due to its nature may be unfairly prejudicial to one or more persons or participants,*"

5.0 PREREQUISITES AND COMMITMENTS

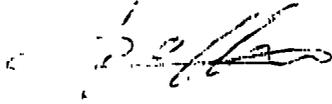
5.2 Full Participants

Pre-requisites

Recommendation: Aventis requests a clarification: Are Full Participants entitled to receive any NCAR, even if their own regulations are not comparable with those of other Full Participant members?

On behalf of Aventis, we appreciate the opportunity to comment on the proposed GHTF documents and are much obliged for your consideration.

Sincerely,



Steve Caffé, MD
Vice President, Head US Regulatory Affairs