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Because health matters

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Date 09-November-2006

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. 2006N-0292

Unique Device Identification; Request for Comments

Dear Sir/Madam:

Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, members of the sanofi-aventis Group, appreciate the opportunity to comment on the above-referenced notice, "*Unique Device Identification.*"

This request from FDA for comments will help the agency understand how the use of a unique device identification (UDI) system may improve patient safety, e.g., by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting.

We have a **comment** to **question #1**:

Question: How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

Comment: Rather than develop a new standard, we have looked for an existing system of international standards for an identification system that can handle the issue of unique device identification. We suggest that the agency look at **ISO 22742:2005** entitled, "**Packaging – Linear Bar Code and Two-dimensional Symbols for Product Packaging.**" This purpose of this ISO standard is to establish the machine-readable (e.g. bar code) and human readable data content of labels applied to product packages. A copy of the standard is available upon request from sanofi-aventis.

This standard:

- Specifies the minimum requirements for the design of labels containing a linear bar code and two-dimensional symbols on product packages to convey data between two trading partners
- Provides guidance for the formatting on the label of data presented in a linear bar code, two-dimensional symbols or human readable form
- Provides specific recommendation regarding the choice of linear bar code and two-dimensional symbologies

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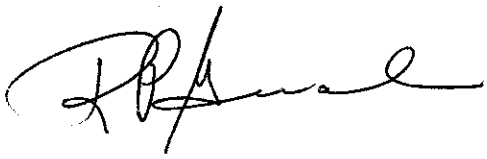
- Specifies quality requirements and classes of bar code density, provides specific recommendations regarding 2D symbologies, which allows a broad choice for general use of scanning hardware (e.g. area imagers, linear imagers, single-line laser scanners, and rastering laser scanners)

- Makes recommendations as to label placement, size and the inclusion of free text and any appropriate graphics. This standard also supports item identification and supply chain processes, at the product package level, such as inventory control, picking, and point of use.

This international standard was published under the auspices of the Technical Committee-122 (packaging). Both the American National Standard Institute (ANSI) and the European Committee for Standardization (CEN) accredit this standard. It does not supersede or replace any applicable safety or regulatory marking or labeling requirements. It is intended to satisfy the minimum product package requirements of numerous applications and industry groups. As such, its applicability is to a wide range of industries, each of which may have specific implementation guidelines. This International Standard is applicable in addition to any other mandated labeling requirements.

On behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, members of the sanofi-aventis Group, we appreciate the opportunity to comment on the notice, "Unique Device Identification."

Sincerely,



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