This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: D4774 – 11 (Reapproved 2017)

Standard Specification for User Applied Drug Labels in Anesthesiology[1]

This standard is issued under the fixed designation D4774; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers the size, color, pattern, and type used on labels applied to unlabeled syringes filled by the users or their agents to identify the drug content. This specification is not intended to cover labels applied by the drug manufacturer.

1.2 The values stated in SI units are to be regarded as the recommended values. The use of inch-pound system values, not being exact equivalents, may result in nonconformance with the standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D996 Terminology of Packaging and Distribution Environments

2.2 *Other Standard:*

Pantone Matching System[3]

3. Terminology

3.1 *Definitions*—General definitions for packaging and distribution environments are found in Terminology D996.

4. Size and Background Color Requirements

4.1 *Label Size*—The labels shall have a nominal length of 25 to 35 mm and a width of 10 to 13 mm.

4.2 *Label Background Color*—The colors and patterns given in Fig. 1 shall be used to distinguish these groups of drugs. The background color shall not interfere with the ability of the user to write information on the label.

4.2.1 *Antagonists*—To denote an antagonist, 1-mm wide diagonal stripes of the agonist color alternating with a 1-mm wide white stripe shall be used. The stripes shall run from the lower left to the upper right at an angle of approximately 45° to the long axis of the label. The name of an antagonist drug shall appear in the center of the label and the striping shall be omitted behind and below the name (see Fig. 2).

[1] This specification is under the jurisdiction of ASTM Committee F02 on Primary Barrier Packaging and is the direct responsibility of Subcommittee F02.50 on Package Design and Development.

Current edition approved Dec. 15, 2017. Published January 2018. Originally approved in 1988. Last previous edition approved in 2011 as D4774 – 11$^{\varepsilon 1}$. DOI: 10.1520/D4774-11R17.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from Pantone, Inc., 509 Commerce Boulevard, Carlstadt, NJ 07072–3098.

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