Designation: D6398 – 08 (Reapproved 2014)

Standard Practice to Enhance Identification of Drug Names on Labels[1]

This standard is issued under the fixed designation D6398; 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 practice covers the shape, size, color, layout, typeface, and barcoding on drug container labels intended for prescription product packaging such as might be used in hospitals, pharmacies, and nursing centers.

1.1.1 This practice does not apply to bulk product shipping containers; in-process transfer containers; or primary, secondary, or tertiary finished goods containers.

1.2 This practice does not apply to over-the-counter drug product labeling.

1.3 This practice does not apply to retail product labeling.

1.4 The values stated in SI units are to be regarded as standard. The values given in parentheses are for information only.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D996 Terminology of Packaging and Distribution Environments

D4267 Specification for Labels for Small-Volume (100 mL or Less) Parenteral Drug Containers

D4774 Specification for User Applied Drug Labels in Anesthesiology

D7298 Test Method for Measurement of Comparative Legibility by Means of Polarizing Filter Instrumentation

2.2 *Other Documents:*

21 CFR 429.12 Packaging and Labeling of Insulin[3]

21 CFR 201.66 Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling[3]

ISO 3864 Safety Colors and Safety Signs[4]

3. Terminology

3.1 General definitions for packaging and distribution environments are in accordance with Terminology D996.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *shape of label*—shape of the label wherein is written the name of the drug, the dosage, and the total contents of the drug in its final form.

4. Significance and Use

4.1 Medication errors occur when users are confused by the similar size, shape, color, typeface, and layout of labels that are used for a range of a manufacturer's drugs with widely dissimilar actions or potencies. The human visual system uses shape, size, color, and typeface in the initial recognition of a labeled drug. (See 9.1 – 9.3.) The use of this human visual system has been described in 21 CFR 429.12 for the labeling of insulin. Using the similar label design, color, and typeface throughout a product line makes identifying an individual drug more difficult.

4.2 The objective of this practice is to provide guidance for the design of drug labels which will enable users to easily distinguish between drugs of differing action or potency. See Note 1.

NOTE 1—For specific requirements for these labels and other features of labels for OTC human drugs, see 21 CFR 201.66.

5. Label Requirements—Panel Shape, Color, and Contrast

5.1 Differing combinations of label shape and color, with differing layouts and text face should be used to provide a readily recognizable combination for each group of drugs with different actions or potency within a manufacturer's range of products. (See Fig. 1.)

5.2 High contrast between the margin of the label and its surroundings and between the drug name and background should be provided.

[1] This practice is under the jurisdiction of ASTM Committee D10 on Packaging and is the direct responsibility of Subcommittee D10.32 on Consumer, Pharmaceutical, Medical, and Child Resistant Packaging.

Current edition approved April 1, 2014. Published April 2014. Originally approved in 2001. Last previous edition approved in 2008 as D6398 – 08. DOI: 10.1520/D6398-08R14.

[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 Standardization Documents Order Desk, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, http://www.dodssp.daps.mil.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.