

New ASTM Standards—Labels in Anesthesiology and Pharmaceutical Packaging

Adding Another Level of Safety in Patient Care

ASTM Subcommittee D10.32 on Consumer, Pharmaceutical and Medical Packaging has recently completed a significant revision to ASTM D4774, Specification for User Applied Drug Labels in Anesthesiology, and approved a new standard, ASTM D7709, Test Methods for Measuring Water Vapor Transmission Rate (WVTR) of Pharmaceutical Bottles and Blisters.

Subcommittee D10.32 is under the jurisdiction of ASTM International Committee D10 on Packaging.

User Applied Drug Labels in Anesthesiology

ASTM D4774, Specification for User Applied Drug Labels in Anesthesiology, originally published in 1988, covers the size, color and pattern, and type used on labels applied to unlabeled syringes filled by users or their agents to identify drug content. According to Delphos Price, a certified registered nurse anesthetist and a liaison from the American Association of Nurse Anesthetists to D10.32, a study done in Delaware was the impetus for the recent important revision to ASTM D4774.

Price says that more than 1,600 labels were collected from 34 clinical sites in the Delaware study, revealing the use of a wide variety of label colors, sizes and information. Data resulting from the study revealed that compliance with the standard in Delaware was less than five percent. This data led to the recent revisions to ASTM D4774.

“The revision of ASTM D4774 was completed after consultation with a variety of anesthesia professionals,” says Price. “There was an overall update and improvement of the information and pharmacology list for each category to reflect pharmacological changes, including additions and deletions, over the years since the development of the standard.”

One of the major changes to ASTM D4774 was the creation of a beta blocker label to reflect the serious nature of this type of medication and the frequency of its use by anesthesia professionals in the preoperative, operative and postoperative phases of patient care.

“The use of standardized labels is one more aid to assist in properly identifying the medications drawn up for a procedure,” says Price. “The use of color labels adds another level of safety through quality improvement for each patient cared for by the anesthesia professional.”

Water Vapor Transmission Rate

Providing a barrier to water vapor at both normal and elevated room temperature and relative humidity is

an essential component for any sort of drug packaging. A series of experiments conducted by the container closure-working group of the Product Quality Research Institute has led to improved methods for evaluating water vapor barrier packages. These methods are detailed in a new ASTM standard, [ASTM D7709](#), Test Methods for Measuring Water Vapor Transmission Rate (WVTR) of Pharmaceutical Bottles and Blisters.

According to Hugh Lockhart, Professor Emeritus, School of Packaging, Michigan State University and chairman of the D10.32 task group that developed [ASTM D7709](#), drug manufacturing and packaging companies will be the primary users of the new standard. In addition, data obtained by the methods in ASTM D7709 will likely be used by government regulatory agencies concerned with the packaging of drugs throughout the world.

While work on [ASTM D7709](#) is now complete, Lockhart says D10.32 requests that those using the methods detailed in the standard report their results to the subcommittee. This would enable continual improvement of the standard. The best way to contribute to the ongoing development of D7709 is to join D10.32 and provide input as a committee member.

“We would ask people to use the method on other package forms and report on their success,” says Lockhart. “We think there is broad application in food and other packaged products, but this has not been proven by direct use on those products.”

To purchase ASTM standards, visit www.astm.org and search by the standard designation number, or contact ASTM Customer Relations (phone: 610-832-9585; service@astm.org). ASTM International welcomes and encourages participation in the development of its standards. For more information on becoming an ASTM member, visit www.astm.org/JOIN.

ASTM Committee D10 Next Meeting: Oct. 30-Nov. 2, October Committee Week, Tampa, Fla.

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