In an industry as complex and regulated as pharmaceutical, locating the right packaging information is sometimes a bigger challenge than designing, sourcing, filling, or labeling the package. The good news is that the maturing of the Internet has made it much easier to find up-to-date information on virtually any packaging-related topic.

The first place to start, particularly for matters relating to regulations, guidelines, and current good manufacturing practices (CGMPs) is FDA’s Web site, www.fda.gov. This Web site has a good search function as well as news, hot topics, and reference sections. The reference section is especially useful because it is divided into seven categories: laws that FDA enforces, the Code of Federal Regulations, the Federal Register, guidance documents, dockets, warning letters, and manuals and publications. The agency also offers a number of free e-mail newsletters, and documents can be downloaded from the Web site at no charge.

Studying the original regulatory documents should be a standard practice for anyone involved in packaging pharmaceutical products because regulatory information from other sources might omit important details, contain inaccuracies, and offer interpretations that are not in line with the agency’s thinking.

The Center for Drug Evaluation and Research (CDER) has its own home page (which can be accessed from FDA’s home page by clicking on “Drugs” under the heading, “Products FDA Regulates”). It lists a number of “Quick Info” links to help find information fast.

The United States Pharmacopeial Convention Inc. (USP, Rockville, MD) provides standards for more than 3800 medicines, dietary supplements, and other healthcare products. This information is published in the USP–National Formulary (USP–NF), the official drug standards compendia. USP also provides about 1300 premier chemical Reference Standards to conduct the tests specified in USP–NF. USP also works in the area of patient safety and maintains records related to medication errors through its Medmarx database. The USP Web site, www.usp.org, offers both a search function and an on-line store where reference standards and publications can be ordered. Fees are relatively low.

Another important source for regulatory information is the United States Consumer Product Safety Commission (CPSC, Washington, DC) Web site, www.cpsc.gov, which oversees child-resistant packaging requirements. A library listing includes headings for official federal information (CPSC regulatory information) and CPSC publications. CPSC also maintains the National Electronic Injury Surveillance System, which collects data from hospital emergency rooms about consumer product-related injuries.

A wealth of domestic and global regulatory information can be found at www.packaginglaw.com, a Web site sponsored by the law firm Keller & Heckman LLP (Washington, DC). It features a different focus topic each month and archives back articles. Other sections include news headlines and an “ask an attorney” service. A search function makes it possible to check the Web site by section or in its entirety.

For topics related to parenteral products, volumes of information can be found at www.pda.org, the Web site of the Parenteral Drug Association (PDA, Bethesda, MD). The PDA Web site also has a good search function, which includes archived material. PDA is an excellent source for information about draft regulatory documents. Particularly valuable are the association’s monthly...
Supplier Web sites can help locate specific details about packaging materials, containers, machinery, and related items.

**Conventional references**

A number of market research firms prepare periodic reports related to pharmaceutical packaging. Freedonia (Cleveland, OH), for example, published a pharmaceutical packaging study in March 2004 and a world pharmaceutical packaging study in December 2003. Report details and ordering information may be found at www.freedoniagroup.com.


Standards organizations also provide essential information. Available in print or CD-ROM formats, Consumer and Healthcare Packaging Standards was published in May 2002 by ASTM International (West Conshohocken, PA). The 366-page book includes 85 of the latest standards on consumer and healthcare packaging, including water vapor transmission of flexible heat-sealed packages for dry products, minimum application torque of Type IA child-resistant closures, seal strength of flexible barrier materials, and detecting gross leaks in porous medical packaging by internal pressurization bubble test.


**General packaging references**

Although pharmaceutical packaging is highly specialized, general references about packaging shouldn’t be overlooked. Highly detailed information about materials, containers, and machinery can be found in books such as The Wiley Encyclopedia of Packaging Technology, Second Edition, published by John Wiley & Sons, Inc. (New York, NY). Approximately 200 experts provided information for about 250 listings spanning all stages of the packaging process from raw materials through final package distribution. Entries cover all major segments, including materials, machinery, containers, components, quality assurance, recycling, and regulations.

Another general packaging reference, the Fundamentals of Packaging Technology, Third Edition, was published in 2002 by the Institute of Packaging Professionals (IOPP, Naperville, IL). Based on a popular four-week course given once or twice per year, the 20-chapter text includes detailed information on packaging materials and container formats, graphic design, package printing and decorating, closures, adhesives, distribution packaging, and the...
package development process.


Standards-setting organizations also offer general packaging information. ASTM, for example, recently published the fourth edition of its ASTM Standards & Other Documents Related to Performance Testing of Shipping Containers and a sixth edition of Selected ASTM Standards on Packaging. The latter defines 78 ASTM standards related to plastics, paper, glass, metals, rubber, and composites used in containers, cushioning, wrapping, barriers, closures, and aids for sealing, utilizing, reinforcing, and handling. The book also includes nine standards from TAPPI (Norcross, GA), a trade association for the pulp- and paper-converting industry. The TAPPI Web site, www.tappi.org, offers a variety of resources, including bulletin boards and an “Ask the Experts” service. The group also archives conference proceedings.

Another group related to shipping standards, the International Safe Transit Association (ISTA, East Lansing, MI), publishes the ISTA Resource Book. It describes testing procedures and provides guidelines for testing to ensure a product will arrive intact at its destination. In addition to developing standards, the group certifies testing laboratories, test laboratory personnel, and packages. Its Web site, www.ista.org, includes discussion forums and a marketplace for procedures and publications as well as conference proceedings.

Another tack to take is packaging material/format oriented websites. These typically are maintained by trade associations such as the Glass Packaging Institute (Washington, DC), www.gpi.org; the Can Manufacturers Institute (Washington, DC), www.cancentral.com; and the Corrugated Packaging Council (Rolling Meadows, IL), www.cpc.corrugated.org.

With dozens of additional Web sites carrying information, researching questions related to pharmaceutical packaging can take a shortcut.

Researching questions related to pharmaceutical packaging can take a shortcut with the dozens of Web sites that carry this type of information.