

# Industry Changes OTC Labels as Deadline Approaches

Hallie Forcinio

Suppliers agree that if you haven't started the process, it's time to get busy.

**W**ith the deadline for conversion to easier to read and understand labels just over six months away, pharmaceutical manufacturers are gearing up to make the labeling changes required on most over-the-counter (OTC) pharmaceuticals shipped on or after 16 May 2002.

Relatively few manufacturers have converted their products' labels to the new format, so it will be a busy fall and winter for pharmaceutical manufacturers and their packaging suppliers.

New and relaunched products already must be in compliance with the Over-the-Counter Human Drugs Labeling Requirements regulation finalized in 1999. Manufacturers of older OTCs, however, have until 16 May to make the change. Shipments made after that date will be considered misbranded if new labeling is not in place. "Although the compliance strategy is not yet fully developed, FDA will be monitoring," warns Gerald Rachanow, regulatory counsel at FDA's Center for Drug Evaluation and Research.

## Meeting regulation requirements

Dubbed the Drug Facts Labeling Regulation after the heading required on a label's information box, 21 *CFR* 201.66 specifies the format, type size, terminology, and sequence of information. According to the regulation, the Drug Facts heading is followed by an Active Ingredients listing that notes the name and quantity of each active ingredient per the dosage unit and its purpose. The listing is followed by Purpose, Use, and Warning sections. Subsequent information blocks include Directions, Other Information, and an Inactive Ingredients list. Manufacturer contact information is optional but recommended.

The regulation requires that labels include a minimum six-point type size with a minimum of 0.5-point leading (the space between lines), and headings must be at least two points larger than the text. The heading Drug Facts must be at least eight-point bold italic and must be larger than any of the other text within the box. Any clear, easy-to-read type style may be used, but type must

be printed in black or another dark color on a white or other light background. Round or square five-point bullets will be used to draw attention to required information. Small packages on which the Drug Facts information occupies more than 60% of the available labeling area are granted a bit of leeway, but their labels still must use at least six-point type for text and seven-point type for headings (21 *CFR* 201.66 [d] [10]).

"The new format formalizes product information and makes it more readable for the consumer," says Michael Hildick, senior vice-president of operations at Natural White (Tonawanda, NY), a maker of toothpaste and tooth-whitening agents, whose fluoridated products must follow the same regulations and good manufacturing practices as pharmaceuticals. "It makes it easier to understand what is in the product and any warnings and information about intended use," he adds. "In the past, a lot of information was mixed together. Now it's categorized and identified better so consumers can pick up the package and find out what they need to know before they use the product. I think [the changes] will be very well received," Hildick concludes.

Natural White is in the enviable position of having completed the transition to its new packaging design. About 10 stock-keeping units (SKUs) were involved. "We kept the same carton size," reports Hildick. "The front panel stayed the same; the back panel was changed to meet the regs," he says. As a small company that relies mostly on advertising in free-standing inserts, "We want eye appeal for the package and to have as much advertising on the product as possible," he explains.

During a period of approximately six months, the company completed the carton designs and had the cartons printed as existing supplies were depleted. "The biggest challenge was the first one," Hildick notes. The design group at Natural White's headquarters in Aurora, Ontario, created the new artwork with assistance from two local design firms (York Design and Jackson Design, Aurora, ON) as well as heavy input from the company's US office and its carton printer (Diamond Packaging, Rochester, NY). The latter offered suggestions for ways to rearrange design elements to

Hallie Forcinio is *Pharmaceutical Technology's* Packaging Forum editor, 4708 Morningside Drive, Cleveland, OH 44109, tel. 216.351.5824, fax 216.351.5684, e-mail editorhal@cs.com.

<b>Drug Facts</b>		<b>Drug Facts</b> (continued)	
<b>Active ingredient</b>	<b>Purpose</b>	<b>Directions</b>	
Benzoyl peroxide 10%.....	Acne treatment cream	<ul style="list-style-type: none"> <li>■ clean the skin thoroughly before applying</li> <li>■ cover the entire affected area with a thin layer 1 to 3 times daily</li> <li>■ because too much drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a doctor</li> <li>■ if bothersome dryness or peeling occurs, reduce application to once a day or every other day</li> <li>■ if going outside, use a sunscreen. Allow benzoyl peroxide to dry, then follow directions in the sunscreen labeling.</li> </ul>	
<b>Uses</b>		<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ treats acne</li> <li>■ dries up acne pimples</li> <li>■ helps prevent new acne pimples</li> </ul>		store at 20-25° C (68-77° F)	
<b>Warnings</b>		<b>Inactive ingredients</b>	
<p>For external use only</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ on broken skin</li> <li>■ on large areas of the body</li> </ul> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ apply to affected areas only</li> <li>■ avoid unnecessary sun exposure and use a sunscreen</li> <li>■ do not use in or near the eyes</li> <li>■ this product may bleach hair or dyed fabrics</li> <li>■ using other topical acne drugs at the same time or right after use of this product may increase dryness or irritation of the skin. Only one drug should be used unless directed by a doctor.</li> </ul> <p><b>Stop use and ask a doctor</b> if too much skin irritation or sensitivity develops or increases</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>		<ul style="list-style-type: none"> <li>aluminum hydroxide gel,</li> <li>bentonite, carbomer-940, dimethicone, glyceryl stearate SE, isopropyl myristate, methylparaben, PEG-12, potassium hydroxide, propylene glycol, propylparaben, purified water</li> </ul>	

Drug Facts information may be arranged in a columnar format to save space, as shown in this sample from FDA's Guidance document.

make the graphics neater and cleaner. To reflect the products' premium positioning among similar products, cartons are offset printed, generally in six to eight colors. Some also include embossing and gold-leaf hot stamping.

Hildick estimates the cost of the re-design and new printing plates at \$3000 to \$4000 per SKU and somewhat higher if all labor hours for discussion time are included.

Most companies that are still working through the process have established project teams and expect to be ready by the deadline. Bayer Corp. (Pittsburgh, PA), for example, has been working on the transition since the regulation was finalized. With multiple products to be converted, it is limiting itself to making the changes necessary to meet the requirements and using a variety of packaging solutions depending on the product involved. "Evaluations are ongoing within the organization to determine best solutions while meeting the Drug Facts text and format requirements," says Joanne Robinett, director of regulatory affairs at Bayer.

As companies embark on the conversion process, questions arise about how inactive ingredients should be listed, especially for drug and cosmetic products

such as dandruff shampoo. If a company makes dandruff-reducing claims on a label, the product is treated as a drug; if it only makes claims about hair enhancement, then inactive ingredients are listed according to cosmetic labeling regulations.

Another commonly asked question is whether the information must appear on both primary and secondary packaging. If a primary bottle is sold in a carton, "only the carton has to have the Drug Facts," says Rachanow. If no carton is used, then the bottle label would carry the information. The Drug Facts must appear only once.

Exemptions and deferrals will be few and far between. "We had about 15 requests for exemptions early on," recalls Rachanow. Most involved requests to use a type size smaller than six points and were rejected. "Manufacturers may just have to increase the size of the package or change to another type of labeling," he says.

It's likely that deferrals will be granted for special cases. One possible candidate is convenience-size packages that hold one or two doses. A petition from Little Drug Stores has asked if some information can be put inside the package because consumer information needs are different when one or two doses are involved versus multiple-dose medication, which may

be taken sporadically during a long period or repetitively until a regimen is completed.

Deferrals also may be granted when the agency knows revised labeling provisions are imminent for a certain class of drug or ingredient. In these situations, the agency "will grant deferrals in advance so pharmaceutical manufacturers won't have to change their labels twice," says Rachanow.

### Packaging solutions

The big challenge is fitting the required information on existing package real estate. "Most people wind up going to a bigger package," says Rachanow. This modification can be accomplished by adding a fifth panel riser to the carton, putting small containers on blister cards, or simply extending the dimensions of an existing package. However, bigger is not always practical from a cost and merchandising perspective.

Other alternatives include using extended-text labels or cartons or reducing the amount of the extra space needed by arranging the information in a column

format. For manufacturers considering the columnar approach, FDA published a final guidance document in December 2000, *Labeling OTC Human Drug Products Using a Column Format* ([www.fda.gov/cder/guidance/3594fnl.htm](http://www.fda.gov/cder/guidance/3594fnl.htm)).

Many suppliers to the pharmaceutical industry have developed creative designs to provide additional label space. One design provides an extended tab on a header card that pulls up to display information (Design Relief header card, Diamond Packaging). Another design adds extra folds to carton flaps (Extended Content Carton, Mebane Packaging, Mebane, NC; Design Relief carton, Diamond Packaging). The advantage of these two expanded-content concepts is that the outer dimensions used in current packaging can be maintained.

Extended-text labels are another option (Text-A-Peel, RxPerts Printing Alliance, Crestview Hills, KY; Reveal Estate, Impaxx Pharmaceutical Group's Label Express, Inc., Orem, UT; 700° + Tamper Evident Design, National Label, Lafayette Hills, PA; multipanel labels, Inprint USA,

St. Charles, MO). Available from numerous suppliers in a variety of peel-up formats, these designs allow the underside of the label to be used and can offer multiple pages in a book-like format or a single, large sheet that unfolds like a map.

Yet another possibility is a prototype carton-insert combination that provides space so information displaced from the carton can be put inside (carton-insert combination, Impaxx Pharmaceutical Group's Arlington Press, Brooklyn, NY).

### Smoothing the transition

Suppliers agree that if you haven't started the process, it's time to get busy. "Assuming you can wait until the last minute and convert is an incorrect assumption," says Des Laffan, general manager at RxPerts Printing Alliance. Because product may be shipped with the old labeling through 15 May 2002, pharmaceutical manufacturers should plan to fill the supply pipeline before that date to exhaust supplies of old stock.

Any structural change should be ma-

chine tested to ensure it will run correctly on the packaging line. Often this means testing, tweaking, and retesting before a design is optimized. New labels not only should be machine tested to ensure efficient application but also should undergo environmental testing to guarantee that the substrate adheres properly for the life of the product.

Suppliers also can use the redesign effort as an opportunity to reduce packaging by eliminating cartons and switching to an extended-text, tamper-evident primary label. Another possibility is to use the redesign to support marketing efforts by incorporating cross-merchandising coupons or bounce-back offers. The redesign also can accommodate source tagging, a process increasingly in demand by retailers who want suppliers to deliver product with preapplied electronic article surveillance tags so retailers won't have to do it at the distribution center or store. Whether adding source tags or not, suppliers may want to ensure that any redesign fits in with superstore requirements related to package size, primary panel orientation, bar codes, and so forth.

Finally, "Explore all options, look at the whole package, including application equipment," advises Neil Sellars, director of product development and marketing at National Label. "It's amazing how many people restrict the design because of equipment," he says. A relatively low-cost investment in equipment can mean the difference between maintaining or even upgrading line efficiency with the redesigned package. **PT**

Circle/eINFO 33

### FYI

#### Dissolution method development workshop

VanKel and the School of Pharmacy of the University of North Carolina at Chapel Hill will cosponsor the Dissolution Method Development for Pharmaceutical Dosage Forms workshop 4-6 December 2001 in Morristown, New Jersey. The workshop will focus on fundamentals of pharmaceutical systems, in vitro dissolution testing, dissolution and bioavailability, and biorelevant dissolution test method development. For more information, contact VanKel, 13000 Weston Pkwy., Cary, NC 27513-2228, tel. 800.229.1108, fax 919.677.1138, [www.vankel.com](http://www.vankel.com).