

UDI Rule Takes Final Shape as Comment Phase Nears End

Medical device makers were urged to move forward with planning for Unique Device Identification (UDI), with the issuance of a final UDI regulation System expected by May 2013, attendees heard at a UDI conference in Orlando last month.

Jay Crowley, senior advisor for FDA's Center for Devices and Radiological Health (CDRH), said companies should not expect an extension of the 180-day comment period on the proposed rule beyond November 7.

"Submit comments. We need your help to make sure this is usable and understandable to all players," Crowley advised the 400-plus attendees.

While the major provisions of the UDI rule are unambiguous, attendees sought clarification on aspects of the regulation and their application to specific use cases. FDA will be hammering out final rule requirements on issues including, Crowley said, an exemption process procedure.

"We received a lot of questions on whether 'my device is exempt.' Once the final rule is in place we can make interpretations on different devices. [But] this [regulation] applies to nearly all devices. UDI will be used by all stakeholders—distributors, GPOs, and hospitals. I wouldn't count on a lot of exemptions—you should assume it applies to your device," Crowley said.

General exemptions listed in the proposed rule could still be changed as well, he noted.

The rule's proposed format for dates on device labels created "a fire storm," Crowley reported, as device makers favored the widely-adopted ISO 8601-2004 standard that expresses the date in an all-numerical scheme.

"This is the most controversial part of the rule. We didn't expect this. I realize for global manufacturers this is extremely problematic. We are not going down this path—we will come up with a better way to do it," he said.

In coming weeks, FDA will publish a list of implants and life-sustaining devices for which the UDI requirement is effective two years after the final rule's publication. Software is a medical device; the agency will come up with a way for applying the unique identifier on Health Information Technology, Crowley said.

UDIs are required on outer packaging, such as boxes and cartons, to allow identification of devices through the supply chain. "If there were no UDI on the outer packaging, the box or other type of container would need to be opened to access it, which could facilitate tampering and contribute to the very problems that the UDI system is designed to remedy," the proposed rule reads.

"You don't need a UDI on the final shipping container. Perhaps this needs more clarity. We look forward to comments," Crowley said in response to an audience question.

Walmart Implements Ecoslide-RX Compliance Pack From Keystone Folding Box

Ecoslide-RX, a pharmaceutical compliance package that has been called "more environmentally sustainable" than traditional packs, will soon be arriving to Walmart's pharmacies.

Walmart will use the pack for repackaging drugs it buys in bulk, in

Legacy Pharmaceuticals is running lines for supplying Walmart with the Ecoslide-RX from Keystone Folding Box.



the business model it employs with the Shellpak format.

Legacy Pharmaceuticals in St. Louis has installed a fully automated line for running the Ecoslide-RX pack for supplying Walmart, and was running product at the end of September, says Ward Smith, director of marketing, Keystone Folding Box in Newark, NJ.

"This is the first adoption of the Ecoslide-RX pack in a commercial application. Product will be on store shelves in the month of October, in a nationwide launch," Smith says.

Introduced in late 2011, Ecoslide-RX is senior-friendly and achieves the Walmart *Continued on page 17*

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highest child-resistance rating of F=1. Customer safety and ease-of-use are two ongoing, previously unmet challenges for environmentally sustainable products in the pharmaceutical industry, the company announced.

"At Walmart, we are dedicated to quality patient care and have proven that adherence packaging assists in these endeavors," said Sandy Kinsey, vice president of pharmacy merchandising for Walmart.

Ecoslide-RX is a solution for prescription products, physician's samples, and clinical trial materials, offering large, easy-to-read type on all sides and clear, simple opening instructions.

The pack tests well among both pharmacists and consumers. Both groups in a recent independent survey gave Ecoslide-RX high marks when graded against competing blister solutions and traditional amber vials. Aside from the product's increased environmental sustainability and lack of associated "landfill guilt"—both groups were impressed with several of Ecoslide-RX's benefits, including:

Ease of Opening. Large, clear directions show users how to unlock the simple child-resistant locking mechanism,

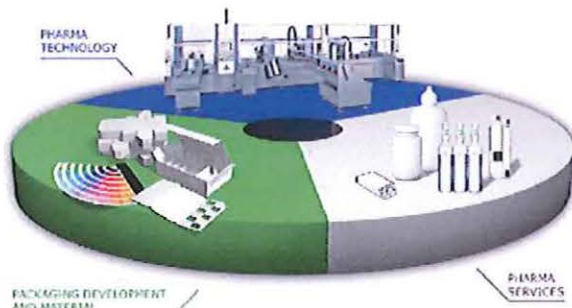


The enclosed blister card remains attached to the Ecoslide-RX carton.

nism, which opens with little force by a thumb press on a release button located on the corner of the carton's front panel. Inside the outer carton is a film/foil, push-through blister card that slides out when the CR lock is released, yet remains connected to the carton at all times. Once open, the pack offers push-through pill access.

Compliance and Safety. Ecoslide-RX offers the compliance and safety benefits that blister packages often present when compared with bottles, including a diminished risk of contamination from dropping or spilling or moisture; increased compliance via a pill reminder/weekly calendar; and additional package printing space enabling large, bold labeling—important for any visually impaired consumers. All of these attributes proved reassuring to pharmacists and consumers participating in the survey.

Ease of Storage/Transport. Compared with amber vials, Ecoslide-RX is more stackable in medicine cabinets and convenient for use in purses and suitcases. Pharmacists noted that the package was large enough to incorporate the range of benefits listed above, yet compact enough to be somewhat discrete.



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