Child-Resistant Packaging Laws Take a Turn

Many of us can remember the first time we reached into our cabinet and took out a bottle of medicine that was packaged in a child-resistant container. It couldn't be opened with a simple turn to the left or flick of the thumb. In the beginning, it took several minutes just to figure out that the cap had some small print on it instructing us to push and turn -- both at the same time!

Now, many years later, we instinctively push and turn because we assume that the container is child-resistant, and we're occasionally stymied by containers that are not, in fact, child-resistant. Although child-resistant (CR) packaging has become a common household, industry, and even regulatory term, we still get confused. Why are some of our drugs packaged in CR packaging while others are not? Why is ibuprofen packaged in a CR container while pseudoephedrine is not? Do we simply turn? Or do we push and turn?

The Consumer Product Safety Commission (CPSC) has issued a proposed rule, which appeared in the Aug. 30, 2000, Federal Register, that may give us the answer, but that also may create some new questions.

Case-By-Case Basis

Under 16 C.F.R. §1700.14(a)(10), CR packaging is required, with very few exceptions, for all oral prescription drug products. All other drug products--non-oral prescription drugs and over-the-counter (OTC) drugs--are reviewed case by case.

Under current law, when an oral prescription drug is given clearance to switch to OTC status, the CR packaging requirement is carried over to the OTC-switched package on a case-by-case basis. Under the CPSC’s proposed rule, the CR packaging requirement in any oral prescription drug product will continue to apply if that drug product, or any other drug product containing an active ingredient of that product, is given OTC status by the U.S. Food and Drug Administration. The proposed rule would only apply to OTC-switched drug products that are oral formulations. Non-oral formulations, (e.g., ointments, topical preparations, etc.), would still be regulated case by case. Additionally, the proposed rule will not apply retroactively; it will apply “prospectively to drug products for which the application for the OTC-switch is submitted to the FDA on or after the effective date of the final rule.”

While we typically think of the FDA as having jurisdiction over drug-related regulatory matters, the Poison Prevention Packaging Act of 1970 empowered the CPSC with the authority to regulate certain standards for drug packaging. Under the PPPA, the CPSC can establish standards for the special packaging of any household substance if it finds that: 1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from personal serious injury or serious illness resulting from handling, using, or ingesting such substance; and 2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance. See 15 U.S.C. §1472(a).

If a company, after filing a new drug application (NDA), is given approval by the FDA for the prescription drug to be switched to OTC status, the CPSC will determine on a case-by-case basis whether or not the OTC-switched drug
should be held in CR packaging. According to the CPSC, the FDA has, since 1976, permitted 22 oral drug products, previously available only by prescription, to be OTC-switched. Of those 22 OTC-switched drugs, the CPSC has required only six to be packaged in CR packaging.

Ibuprofen, for example, became an OTC drug in 1984. However, it wasn't until 1989, after incidents of serious injuries to children had been reported, that the CPSC determined that ibuprofen's level of toxicity and widespread use was so great that it must be packaged in a CR format. Since that time, the CPSC staff has focused on active ingredients in drug products that appear to be heading in the direction of OTC status, and imposes CR requirements, if deemed necessary, soon after OTC status is obtained.

Regulating a Class of Products?

The CPSC believes that under its proposed rule—requiring all oral prescription drugs to maintain their CR packaging requirements after they attain OTC status—the agency will better protect children by eliminating any time period before the CPSC imposes a CR packaging requirement for an OTC-switched drug. During such a period of time, the CPSC asserts, children are exposed to non-CR OTC packaging that holds an active ingredient with the same toxicity as the drug had in prescription form.

In its proposed rule, the CPSC points out that, when FDA considers granting a prescription drug OTC status, the agency is concerned primarily with whether or not the drug is safe and effective when self-administered by a consumer in a proper manner; it does not necessarily evaluate whether the drug product would be toxic to a child if unintentionally ingested. Consequently, the CPSC believes that OTC status should not diminish the need for OTC CR packaging.

While drug manufacturers and packagers are equally concerned with ensuring that drugs are packaged in a manner that effectively protects the safety and welfare of children, industry believes that the CPSC's change in position—from a case-by-case approach to a blanket requirement that all OTC-switched drugs maintain CR packaging—is too far-reaching. Comments filed by industry with the CPSC question whether the PPPA gives the CPSC the authority to categorize all future OTC-switched drugs as a “class” of products that, unless exempted by the CPSC, must be packaged in CR packaging. Further, industry points out, the PPPA explicitly grants the CPSC authority to regulate a household substance that presents a threat, due to its packaging, to children; the act does not extend to the CPSC the authority to regulate a class or category of products. Under the proposed rule, the CPSC would, in effect, be regulating a broad range of drug products, many of which may not present a risk of serious injury or illness to children.

Exemption Scheme

Under the PPPA, products that do not pose a risk of serious personal injury or serious illness to children may be exempt from CR packaging requirements. The CR exemption may also apply if drug packaging companies can prove that CR packaging is not technologically feasible, practicable, or appropriate for the substance. See 16 C.F.R. §1702.

In practice, companies submit exemption petitions to the CPSC, and will only obtain exemption status if they can prove that their drug products will not cause serious injury or illness, or that CR packaging is not technologically
feasible, practicable, or appropriate for the substance. In the Aug. 30, 2000, Federal Register, the CPSC stated that “Currently, 18 oral prescription drug products and several OTC formulations of aspirin, acetaminophen, and iron have been exempted from the CR packaging requirements.” This statement seems to imply that the CPSC believes the exemption process to be a viable option for a company that believes its product should not be packaged in CR packaging; however, industry points out in its response to the proposed rule that, “it is not aware of any CPSC granted exemption since at least 1990.”

Under the proposed rule, the CR exemption process would remain in effect; however, the CPSC has proposed to revoke 16 C.F.R. §1702.16(b), which states that the CPSC shall deny any CR exemption petition that is submitted if the FDA has not approved the new drug application. This revocation would enable manufacturers to obtain a CPSC exemption decision prior to seeking FDA approval to switch a prescription drug to OTC status.

While the repeal of Section 1702.16(b) would benefit drug manufacturers in expediting the process of possible exemption, industry has expressed concern with this proposal. Even if a company files an exemption petition to switch a drug, the company may not have time to plan for the packaging and marketing of the product if and when FDA approves the OTC-switched status. Industry has submitted comments to the CPSC regarding the exemption process and has asserted that the procedure would only have significance if the CPSC entertained a petition a year or so before the NDA is even filed. This would provide manufacturers with direction early on in the development of the package, such as whether or not the packaging will have to satisfy the CR packaging requirements under Title 16. However, manufacturers are also concerned that filing an exemption petition with the CPSC in advance of the NDA would prematurely reveal a company’s business strategy, and has called for the CPSC to examine this issue before it abandons its case-by-case analysis of CR packaging.

Comments filed by industry also assert that, under the PPPA, the CPSC has the responsibility to require “special” packaging only in those cases where it is needed to protect small children from serious injury or illness. However, it is argued that the proposed rule improperly shifts the burden to the manufacturers and packagers to prove to the CPSC that their products do not pose a threat of injury or illness to children. The proposed rule does not disturb some viable options, created under the PPPA and subsequent regulations under Title 16, to manufacturers and packagers of OTC products that are required to have CR packaging. Specifically, if the manufacturer or packer supplies a popular size package in CR packaging, it is permitted to supply the same product in non-CR packaging, as long as the non-CR packaging bears a conspicuous label stating “This package for households without young children.”

Assuming the CPSC’s proposed rule is made final, some will continue to assert that the CPSC has overstepped its authority. The rest of us will simply push and turn.