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# CLIENT ALERT

## In The Wake of Recent Supreme Court's Decisions, FDA Proposes Change to Generic Drug Labeling Rule

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**On November 13, 2013, the U.S. Food and Drug Administration (FDA) proposed a regulatory change that would allow generic drug manufacturers to update their labels without waiting for the brand-name manufacturer to do so first. This shift follows two recent Supreme Court decisions, *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013) and *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which both held that tort claims against generic pharmaceutical manufacturers regarding the adequacy of the label were preempted because generic manufacturers were essentially powerless under federal law to change the label. In contrast, the Supreme Court held in *Wyeth v. Levine*, 555 U.S. 555 (2009) that branded drug manufacturers are generally not afforded the same protection. Although generic drug manufacturers have generally been successful at avoiding tort liability for labeling issues thus far, the proposed rule may eliminate their preemption defense and expose them to lawsuits that could have been dismissed quickly under the old rule.**

**Current regulations allow a new drug application holder to make certain labeling changes in the interest of public health based on newly-acquired information. The label can be changed once the FDA receives an application called a "changes being effected supplement" (CBE-0 supplement). Under the proposed rule, generic drug manufacturers would be permitted—and in fact, required—to submit CBE-0 supplements as well. If a generic drug manufacturer learns of new information relating to the safety or effectiveness of the product and that should be reflected in the drug product's label, that manufacturer would be required to propose appropriate revisions to the product's label.**

**When proposing a labeling change, a generic drug manufacturer would have to submit the proposed change, along with the basis for the change and supporting data, to FDA and the NDA holder. If NDA approval for the reference listed drug (RLD) has been withdrawn for reasons other than safety or effectiveness, any entity that has an application for drug products containing the same active ingredient could submit comments to FDA on the labeling change.**

**FDA will approve the change proposed in the CBE-0 upon approval of the same labeling change for the RLD. Once a CBE-0 supplement is approved, other ANDA holders must submit their own CBE-0 supplements containing the labeling revisions within 30 days of FDA posting its approval.**

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**November 2013**

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- FDA Proposes Rule Imposing New Requirements for Manufacturing Practices, Hazard Analysis, and Preventive Controls for Animal Foods
- CPSC Approves Publication of Proposed Voluntary Recall Rule
- Google's Book-Scanning Program is Ruled 'Fair Use'
- In The Wake of Recent Supreme Court's Decisions, FDA Proposes Change to Generic Drug Labeling Rule

**Just as with branded drug manufacturers, generic drug manufacturers could begin distributing a drug with a revised label once the CBE-0 is received by FDA. Accordingly, there may be periods when therapeutically equivalent drugs bear different safety-related labels, albeit temporarily. During these periods, a branded drug's label could differ from that of its generic counterparts, which could in turn differ from each other. While previously, such a disparity would allow the FDA to seek to withdraw approval of an ANDA, the proposed rule would provide an exception for generic drug labels that are temporarily inconsistent with the RLD's label due to safety-related labeling changes submitted by the ANDA holder in a CBE-0 supplement.**

**In order to alleviate the risks of having the same products with different labels, FDA further proposed that while the agency is reviewing a CBE-0 supplement, FDA would post the revised label information publicly on the Internet. The CBE-0 filer must verify that the posted information is complete and accurate and contact FDA regarding any errors within five business days of the online posting.**

**Comments to the proposed rule are due by January 13, 2014. The rule will be effective 30 days after the final is published in the Federal Register. The new requirements will apply to any submission received by FDA on or after that date.**

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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