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FDA Proposes New Rules for Prescription Drug Labeling

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On May 31, the FDA issued a proposed rule to amend prescription drug labeling regulations to require a new type of Medication Guide, specifically a Patient Medication Information guide, for essentially all FDA-approved prescription drugs and biological products administered in an outpatient setting. The proposed rule intends to improve patient access to readable, consistent, and understandable information about his/her prescribed medications, and thus improve patient outcomes.

Under the proposed rule, the Patient Medication Information guide would create a standardized, one-page document that provides patients with timely and essential information about their medication in an easy-to-read format.

This proposed rule will be important for pharmaceutical and biologics manufacturers to follow if finalized and is open for public comment until November 27. For more information about the proposed rule, please contact judith.ogrady@troutman.com.

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