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CLIENT ALERT

New FDA Label Change Rule

Aug.22.2008

The FDA has posted on its website a final rule regarding label changes for drugs, biologics and medical devices. The new rule allows manufacturers to change a product's label to reflect newly acquired information or to add or strengthen language regarding contraindications, precautions, warnings or adverse reactions, provided that there is a sufficient causal association with the product. The new rule allows manufacturers to submit these label changes through "changes being effected," or CBE, supplements, rather than through prior approval supplements. FDA's rationale for this change was to ensure that scientifically accurate information appears on FDA approved labeling.

Consumer advocacy groups argue that the new rule sets a higher standard for adding new safety information to labeling, and thus shields manufacturers from product liability. FDA disagrees, stating in the preamble to the regulation that the new rule merely formalizes FDA's existing labeling standards and policies, and in no way changes the labeling standards under which manufacturers are required to provide warnings regarding risks.

FDA Final Rule - Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices [PDF]

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