SpencerFane®

Advantage CLE: FDA 101: Regulatory Review and Exclusivities for Drug and Biologics Patent Litigation

June 18, 2026
12:00 pm CDT - 1:00 pm CDT

This program provides an overview of how the U.S. Food and Drug Administration fits into the overall regulatory oversight of the biotechnology and drug industry. Our discussion of key sources of FDA law includes an overview of regulated products, general requirements for marketing including clinical studies, and special programs such as orphan drugs to consider, and will highlight the intersection of FDA regulation with biologics litigation under the BPCIA, emphasizing the need for coordinated strategy between FDA regulatory and patent litigation teams to effectively serve biopharma clients.

See the full Advantage CLE 2026 schedule here.

Continuing Legal Education (CLE) credits are pending in Arizona, California, Colorado, Florida, Kansas, Minnesota, Missouri, Nebraska, Nevada, New Mexico, New York, Oklahoma, Tennessee, Texas, and Utah. CLE credit application and approval processes vary per state and may not be available after certain state deadlines. Please email education@spencerfane.com if you have questions about credits.