

OUR PRACTICE

OTC and Prescription Pharmaceuticals

Baker Donelson attorneys regularly advise clients in all segments of the pharmaceutical industry, including both generic and branded pharmaceutical manufacturers. Our practice involves development and execution of regulatory compliance strategies for products subject to the FDA's New Drug Approval (NDA) and Investigational Drug (IND) processes. These strategies often involve responses to establishment inspections, recalls and Warning Letters.

Over-the-Counter Pharmaceuticals

Baker Donelson attorneys advise clients broadly in the over-the-counter (OTC) pharmaceutical industry including branded and private label monograph drugs, drugs that have "switched" from prescription to OTC status and homeopathic drugs. We regularly review advertising and label copy for both our clients and their competitors regarding regulatory compliance, claim substantiation and other competitive issues. We assist clients in proceedings before the National Advertising Division (NAD) and the Council of Better Business Bureaus as well as appeals to the National Advertising Review Board (NARB).

Activities include:

- Actively assisting potential investors in reviewing regulatory history, labeling and advertising for monograph drugs, as well as drugs approved under both the NDA and Abbreviated New Drug Application (ANDA) premarket approval systems.
- Providing guidance on country of origin, import/export requirements pertaining to ingredients and finished products, Good Manufacturing Practices (GMPs) and other matters.
- Collaborating with our clients' operations personnel in the development of supply agreements, indemnities and commercial intelligence on a worldwide basis.
- Efficiently assisting clients in products liability, class action and mass tort litigation as a function of our familiarity with the regulatory environment.
- Regularly supporting pharmaceutical clients in the development and/or defense of trademarks, trade dress, advertising, broadcast network clearances and managing branded and store brand competitive challenges.
- Creating risk-management strategies for products with complex regulatory profiles.