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Drug Product Development and Approval Strategies

One of the core functions of Food and Drug Administration (FDA) is to review marketing applications for regulated products to assure their safety, efficacy, and compliance with other regulatory standards. While this is fundamentally a science-based function, the statutory and regulatory rules the FDA must follow have proliferated, public and congressional scrutiny has intensified, and the amount of time, effort, and money required to obtain FDA approval has skyrocketed. Thus, product sponsors frequently encounter situations with the FDA that require legal knowledge and specialized advocacy skills to keep an application on, or return it to, a successful approval pathway. We advise and assist companies in their dealings with the FDA at all stages of product development and FDA review, covering pre-clinical testing, human safety and efficacy studies, development of appropriate application strategies, and the FDA review process itself.

For new drugs, we work closely with clients' in-house regulatory and scientific personnel and their outside technical consultants to prepare the least burdensome development and approval strategies, and to ensure that the agency's review of product applications is conducted in conformity with the proper scientific, legal, and regulatory standards.

Contact Us

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