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| **ㅡ**ABOUT YOUR COMPANY | Baker McKenzie is one of the largest international law firms. Founded in 1949 under the name Baker & McKenzie, it has over 70 offices in over 40 countries and employs more than 6,500 lawyers. |
| **ㅡ**AREAS OF FOCUS | Baker McKenzie's regulatory team can help you navigate the complex regulatory landscape of the retail, cosmetics, nutritional, pharmaceutical and medical device, generic products, and food and consumer packaged goods sectors.We are forward thinking and vigilant, staying abreast of applicable laws and regulations to provide clients current and forward-thinking advice and counsel across a broad range of issues.Our key areas of support include:transactional due diligence and post-acquisition support for business growthrestructuring strategies including investments, M&A and divestiturescompliance matters including audits, navigating notices from regulatory agencies, proactive compliance programscross-border issues for clients and regulatory issues in other jurisdictionsBiopharmaceuticals and Medical DevicesWe assist clients in the product development stage through commercialization and product launch. We carefully review necessary filings, provide research as well as clinical trial guidance and support, navigate meetings with the FDA, and assist in pre-launch planning, labeling, advertising and promotional strategies and materials review, and FDA enforcement.Additional areas of support include:manufacturing and supply agreements with focus on potential cross-border issues impacting supply chain footprintrequired certifications and additional areas of compliance, specific to medical devicescompliance programs and ready support from our Litigation & Disputes for False Claims Act disputesCosmetics and FoodWe have extensive experience in products regulated under the Federal Food, Drug & Cosmetic Act and the Fair Packaging & Labeling Act. We work closely with clients as advisors in reviewing products they manufacture, distribute or sell for compliance with regulatory guidelines including additives, coloring and any materials along their supply chain used in production.Our team works extensively with clients during product development, in labeling, advertising and marketing promotional strategies as well as cross-jurisdictional regulatory issues, supply chain issues and agreements, distributor agreements and more.We also work in conjunction with our Litigation & Disputes team in defense of claims of mislabeling, false claims, and comparative advertising. |