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| **ㅡ** ABOUT YOUR COMPANY | 가로선  RegTox Solutions is a unique scientific and regulatory consulting company that assists companies from around the world comply with various regulations in the United States and Canada. We primarily help companies in the following industries: cosmetics, dietary supplements, and food ingredients. As a smaller firm, we provide industry-leading expertise at competitive rates.  Companies seek our expertise for a wide-range of regulatory compliance questions, ingredient and product safety assessments, label reviews, product/marketing claim evaluations, writing pre-market dossiers to US Food and Drug Administration (US FDA) and Health Canada, comprehensive literature reviews of scientific data, drafting white papers, as well as various other project needs. |
| **ㅡ** AREAS OF FOCUS | 가로선 California Proposition 65 ComplianceUSA This regulation applies to all products being sold into the State of California and is a separate requirement from any other regulations (*i.e.*, US FDA). We conduct product formulation reviews, exposure assessments, Safe Habor Level derivations, and determine if Prop 65 warnings are required for products to protect firms from costly enforcement activities. Cosmetic RegulationUSA/Canada RegTox assists overseas companies comply with U.S. cosmetic requirements, including MoCRA (Modernization of Cosmetics Regulation Act of 2022), which requires the registration of cosmetic producing facilities and listing cosmetic products sold into the US. Requires a U.S. agent to make submissions. Also, label compliance reviews, safety assessments, and product notifications (Health Canada). Continued…Food Additives, IngredientsUSA/Canada Food additives and ingredients require compliance with US FDA and Health Canada requirements prior to marketing in these jurisdictions. Ingredients that have not been previously approved or permitted require pre-market authorization. In the USA, this is typically through the Generally Recognized as Safe (GRAS) process, and in Canada through the Novel Foods program. RegTox assists companies in determining the regulatory status of their ingredients, whether pre-market authorization is required, what data requirements are necessary to meet the regulatory standard, compiling and drafting the necessary documentation and liaising with government officials prior to submission, as well as during the review process. Dietary SupplementsUSA/Canada RegTox supports companies intending to market dietary supplement products in the USA and Canada by evaluating the regulatory status of the ingredients and determining whether pre-market authorization or notification is required, and assisting in those processes. RegTox also conducts label compliance reviews and safety assessments. |