

DIETARY SUPPLEMENTS AND NEW DIETARY INGREDIENTS

Regulatory Services

The best strategy for market success of your dietary supplement is regulatory preparation prior to manufacturing, marketing, and selling your product. The consequences of a lack of preparation can lead to hundreds to thousands of dollars spent to re-label products, destruction of product, or worse, criminal penalties whether selling your product in the US or the EU. In the EU, regulation of food supplements and tradition herbal remedies is complex and often controversial; the requirements are often underestimated by those wishing to place new supplements on the market. toXcel can provide scientific expertise and regulatory guidance in both the USA and the EU to help mitigate your risks by providing the following services:

- Review labels and claims for acceptable representation
- Review marketing materials for accuracy and acceptable representation
- Literature review to support claims or history of safe use
- Obtain marketing authorization (license) of food/dietary supplement or health food in the EU
- cGMP audits
- Determination of a legal ingredient for the US market
- Determination of “new” dietary ingredient status
- Premarket review of safety to identify which non-clinical safety studies may be necessary for a “new” dietary ingredient
- Placement, planning, protocol development, monitoring, and auditing of non-clinical studies with GLP compliant laboratories
- Review and evaluation of non-clinical final study reports
- Review existing non-clinical safety programs
- Gap analysis for compliance with FDA’s New Dietary Ingredient Regulations
- Review of adverse events reports
- Liaison with FDA
- Expert Witness
- Due Diligence

Let our team of expert scientists and regulatory professionals help you find a cost-effective route to product approval.

For further information, contact Alan Katz at (703) 754-0248 extension 111 or at Alan.Katz@toxcel.com.

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