



## Dietary Supplement Compliance Set-up Services Action Items

### Initial Consultation and Assessment

- **Schedule Initial Meeting:** Arrange a meeting with the client to understand their product offerings, goals, and specific needs.
- **Collect Product Information:** Gather detailed information on product formulations, ingredients, and intended health claims.

### Regulatory Guidance and Strategy

- **Review Product Formulations:** Analyze the ingredients and formulations to ensure compliance with FDA regulations and DSHEA.
- **Develop Compliance Strategy:** Create a detailed compliance strategy tailored to the client's products and market objectives.

### Labeling and Documentation

- **Design Label Template:** Develop a compliant label template including Supplement Facts panel and other required information.
- **Review and Revise Labels:** Work with the client to finalize and approve the product labels.
- **Prepare Documentation:** Compile necessary documentation for regulatory submissions, if required.

### Ingredient and Claims Analysis

- **Verify Ingredients:** Check that all ingredients are approved for use in dietary supplements and assess any potential risks.
- **Assess Health Claims:** Review proposed health claims and ensure they are compliant with FDA regulations and substantiated by evidence.

### Quality Assurance and Control

- **Implement Quality Management Systems:** Set up quality assurance processes and protocols to ensure product consistency and safety.
- **Audit Manufacturers:** Evaluate and select manufacturers based on compliance with Good Manufacturing Practices (GMP).



### Training and Education

- **Develop Training Materials:** Create educational materials covering dietary supplement regulations, labeling, and compliance practices.
- **Conduct Training Sessions:** Provide training sessions for the client's staff to ensure they are well-informed about regulatory requirements.

### Post-Market Surveillance and Compliance

- **Establish Monitoring Processes:** Set up processes for monitoring product performance and customer feedback.
- **Prepare Adverse Event Reporting Procedures:** Develop procedures for tracking and reporting any adverse events related to the dietary supplements.

### Ongoing Support and Updates

- **Set Up Regular Check-Ins:** Schedule periodic meetings to review compliance status and address any emerging issues.
- **Monitor Regulatory Changes:** Stay updated on regulatory changes and inform the client of any new requirements or standards.

### Final Review and Approval

- **Conduct Final Compliance Check:** Perform a comprehensive review to ensure all aspects of compliance have been addressed.
- **Obtain Client Approval:** Get final approval from the client on all documentation, labels, and compliance strategies.

To avail of our professional services kindly contact [hello@consultareinc.com](mailto:hello@consultareinc.com) or call 1-202-982-3002