7150 East Camelback Road, Suite 444
Scottsdale, AZ 85251
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GARG LAW
WHAT WE DO AND WHO WE SERVE

Garg Law is exclusively dedicated to FDA regulatory compliance, specializing in product compliance and enforcement issues. Specifically, we represent a global client base, across all FDA categories: foods, supplements, beverages, cosmetics and personal care products, OTC drugs, medical devices, and animal and veterinary products.

We support product development issues such as regulatory classification, approvals and permits, advertising/labeling and marketing compliance, product safety, manufacturing compliance, supply chain issues and agreements, and the like. We also provide counsel on enforcement actions including recalls, import/export matters such as import detentions, import refusals, reconditioning proposals, and removal from Import Alert, FDA inspections, Warning Letters, and Proposition 65. Where there is overlapping regulation by other agencies (CBP, EPA, CPSC, TTB, USDA), we also provide legal advice and counsel.

Our clients include foreign and domestic businesses, manufacturers, distributors, retailers, importers, exporters, trade associations, foreign governments, and investment and private equity firms.

Our goals are to consistently produce exceptional results, ensure the highest levels of client satisfaction, and develop long-term relationships.

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Our specific areas of practice include the following:

1. **Foods, Dietary Supplements, and Beverages**

We provide counsel on FDA, USDA and EPA regulation of foods, dietary supplements, and beverages. This work includes:

- Assisting companies in determining regulatory classification, pathways, and product compliance requirements
- Reviewing product labeling, claims, websites, and other promotional material for FDA compliance
- Assisting with product safety compliance issues, such as product recalls, safety assessments of food and beverage additives and ingredients, and California Proposition 65
- Counseling on Food Safety Modernization Act (FSMA) requirements, including Foreign Supplier Verification Program (FSVP) plans and the Voluntary Qualified Importer Program (VQIP)
- Advising on compliance with current good manufacturing practices, FDA inspection practices, and recordkeeping and traceability requirements
- Management of third-party laboratory testing
- Management of FDA inspections and responses to Warning Letters, untitled compliance letters and Forms FDA-483
- Management of import detentions, import refusals and requests for reconditioning
- Providing counsel on Import Alerts, including petitioning companies from removal from Import Alert, and other import/export issues
- Assisting with petitions for mitigation of liquidated damages assessed by U.S. Customs
- Assisting with foreign and domestic food facility registrations and U.S. agent representation

We also assist with USDA/TTB/EPA/CPSC and other regulatory agencies affecting these goods.

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2. Cosmetics and Personal Care Products

We provide counsel on the FDA regulation of cosmetics and personal care products. This work includes:

- Assisting with regulatory classification (e.g. cosmetics vs. drugs), related compliance requirements, and business risk management
- Counseling on safety and testing of ingredients, including California Proposition 65
- Assisting with color additive regulations and batch certification testing requirements
- Assisting with good manufacturing practices and recordkeeping requirements
- Counseling on pre- and post-market responsibilities
- Managing product recalls, including determining the possibility of limiting recall scope, drafting FDA and consumer notifications, and recall termination processes
- Assisting with import/export issues
- Management of third-party laboratory testing
- Management of FDA inspections and responses to Warning Letters, untitled compliance letters, and Forms FDA-483
- Management of import detentions, import refusals, and requests for reconditioning
- Providing counsel on Import Alerts including petitioning companies from removal from Import Alert, and other import/export issues
- Assisting with petitions for mitigation of liquidated damages assessed by U.S. Customs

3. OTC Drugs

We provide counsel on FDA regulation and enforcement of OTC Drugs, including:

- Assisting with pre-launch compliance, including providing counsel on marketing products under OTC drug monographs, assisting with FDA-compliant labeling and reviewing ingredient and packaging issues
- Counseling on drug registration and listing

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- Counseling on GMP matters, including managing third-party laboratory testing
- Counseling on post-market compliance
- Managing product recalls, including determining the possibility of limiting recall scope, FDA and consumer notifications, and recall termination processes
- Management of FDA inspections and responses to Warning Letters, untitled compliance letters, and Forms FDA-483
- Management of import detentions, import refusals, and requests for reconditioning
- Providing counsel on Import Alerts, including petitioning companies from removal from Import Alert, and other import/export issues
- Assisting with petitions for mitigation of liquidated damages assessed by U.S. Customs
- Assisting with import/export issues

4. Medical Devices

We provide counsel on FDA regulation and enforcement of medical devices, including:

- Providing counsel on FDA device classification, and applicable regulatory compliance requirements
- Advising on pre- and post-distribution issues regarding the labeling, advertising, promotion, and import of medical devices
- Preparing and filing 510(k) premarket notification applications to FDA
- Managing risks associated with and responding to FDA enforcement and advisory actions, including Warning Letters and untitled compliance letters
- Preparing for and managing FDA inspections, including conducting pre-inspection audits; assisting during inspections; and drafting responses to Forms FDA-483 (inspectional observations)
- Conducting product recalls and other field actions

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- Assisting with medical device listing and establishment registration requirements for foreign and domestic businesses, including U.S. agent representation

- Working on medical device import and export issues, such as export of unapproved devices, import detentions, Import Alerts (automatic detention), import for export, re-importation, and gray-market or parallel market import issues

5. Beverage Alcohol

We provide counsel on TTB compliance issues, including:

- Identifying whether a beverage alcohol product requires an Alcohol and Tobacco Tax and Trade Bureau (TTB) permit

- Preparing and filing TTB permits

- Advising and reviewing Certificates of Label Approval (COLA)

- Advising on joint oversight and regulatory compliance requirements by FDA and TTB, as applicable

6. USDA Compliance

We provide counsel on USDA compliance issues including:

- Identifying whether a FDA-regulated product requires a USDA permit

- Filing, renewing, and amending a USDA permit

- Advising on research permits for regulated materials

- Advising on USDA regulation of plant and seed materials

- Assisting in response to Emergency Action Notifications (EANs)

- Advising on USDA compliance requirements related to pests and/or violative materials in FDA-regulated goods

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7. Electronic Products

Our work in this area includes:

- Evaluating a product to determine whether it is a radiation-emitting electronic product and whether the product is subject to a product-specific performance standard
- Advising on applicable compliance requirements
- Assisting with the importation of radiation-emitting electronic products
- Advising on product certification requirements

8. EPA and CPSC Requirements

Garg Law also assists with other agency requirements, including EPA and CPSC, where applicable. Specifically, we advise on pesticide residue and tolerance questions related to foods and agricultural products. We also advise on CPSC compliance requirements, as they relate to FDA products, such as child resistant packaging regulations.

9. Due Diligence

We work with large brands, corporate law firms and investment companies, where we conduct regulatory due diligence assessments on targets before acquisition or investment.

We evaluate regulatory compliance portfolios, and produce timely, productive and efficient reviews and reports based on specific client needs.