Alimentix

Minnesota Diet Research Center

Alimentix is a comprehensive clinical investigation center conducting research and clinical trials for foods, food ingredients, dietary supplements, natural products, low risk medical devices and over-the-counter (OTC) pharmaceuticals. Alimentix evaluates products to substantiate "health effect" claims by independently conducting timely, scientifically designed literature research and clinical trials at a reasonable cost. With thousands of new products entering the marketplace each year, the need to substantiate health claims with scientifically well-tested data and to communicate this information clearly and accurately in a truthful and not misleading manner to scientists, regulators and consumers is steadily increasing.

Alimentix Expertise

Product Types

- Finished Foods
- Functional Ingredients
- Natural Products
- Food Supplements

Document Types

- Generally Regarded As Safe Reports
- Literature Reviews
- Manuscripts
- Monographs

Study Types

- Taste Studies
- Human Factors Engineering/Use Studies
- Satiety Studies
- Medical Devices (low risk, non-complex)
- Pharmaceuticals (low risk, OTC)
- Label Comprehension Studies

Specific Experience Includes:

- Developing detailed study protocols
- Designing customized diets
- Creating customized questionnaires
- Monitoring studies
- Conducting statistical analyses
- Assisting with study publishing

Food Research

We offer clinical, regulatory and quality affairs expertise in conducting clinical trials and human use investigations. We excel by providing innovative, cost effective and increasingly virtual options to complete research with speed and accuracy in order to enable our clients to market products with appropriate clinical data and regulatory documentation supporting all claims.

Claim substantiation

Manufacturers and businesses using health effect, structure-function and end-user claims for marketing require claim substantiation to satisfy both stringent regulatory requirements and savvy, knowledge-thirsty consumers. Making a suspicious claim may result in poor market acceptance, product recalls, or irreparable harm to a company's reputation. Alimentix fulfills this growing need by providing comprehensive, high quality, rapid and cost-effective clinical research for food, ingredient, dietary supplement, natural product and OTC drug trials.

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Additional Services Offered

Project Types

- Data Abstraction and Analysis
- Ingredient Assessments
- Competitive Landscape Analysis
- Claim Substantiation Matrixes
- Product Fact Books
- Study Summaries, Analyses
- Evidence-Based Nutritional Profiles
- Slide Decks and Presentations

Medical and Scientific Affairs

- Sales and Marketing Support
- Frequently Asked Questions
- Promotional Material Review
- Standard Response Letters to Medical Inquiries
- Consumer-Directed Content Development
- Corporate Wellness Support
- Recipe Formulation Analyses, Suggested Revisions

Clinical Affairs

- Protocols, Informed Consents
- Customized Diets
- Case Report Forms and Databases
- Clinical Study Training
- Trial Registration
- Subject Recruitment
- Monitoring and Data Collection
- Statistical Analyses
- Adverse Event Reporting
- Clinical Report Writing
- Regulatory Submissions
- Product and Publication Support

Regulatory Affairs

- Claim Substantiation
- GRAS Panel Meetings
- New Dietary Ingredient Documents
- OTC Drug Label Registration

Quality Affairs

- SOPs, Work Instructions and Forms
- Risk Management

Case Studies

Safety Reporting for Dietary Supplement

Large, global company required post-market surveillance of all safety reports for new dietary supplement food product. Developed a system to track adverse events (AE) and communicate results. Established call center to log, categorize, track and report all AEs using downloadable access to provide monthly reports and multi-year safety overviews to develop individual categories and statistical trends analyses. Provided subject matter expertise and improved productivity of corporate team. Novel scientific observations, recorded in real time, lead to comprehensive summaries and reports for submission to FDA or others to meet safety reporting requirements.

GRAS Dossier for Food Additive

Large, global food company requested GRAS dossier and panel meeting for specific food ingredient. Created a GRAS dossier based on data, testing, company and public literature related to food ingredient. Organized and convened a panel of global experts on food ingredient. After the GRAS meeting, dossier review and follow-up actions, expert panel agreed food ingredient was safe for human consumption. The approved FDA GRAS submission led the company to safely market the food ingredient in the United States.

We look forward to being a part of your next endeavor!
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