Headline: Frestedt Incorporated Provides Expert Safety Information Services

Subheader: Frestedt Expands Clinical Safety Research

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Whether the information is related to COVID-19, brain tumor clinical trials or the safety of a new food ingredient, Frestedt Incorporated interprets complicated scientific and medical data and is excited to announce an expansion to our clinical safety information services.

Scientific literature is one critical place to search for safety information. Frestedt has developed a proprietary and standardized, ISO-9001-certified research process to rigorously evaluate published literature. The Frestedt literature search style applies expertise gained over 40 years and can be modified to meet client needs for any given project. This search style incorporates thorough consideration of appropriate search terms and connectors as well as literature appraisal steps considering the Level of Evidence offered by each article (i.e., meta-analyses of human clinical trials are assigned greater weight than articles about individual case studies). Our approach is designed to focus on human clinical data to determine safety in new products. The need for *in vitro* cell/tissue assays and *in vivo* animal research data are also important; however, these data are poor substitutes for actual human clinical trial data or human experiences with any given product.

Frestedt is focused on developing clear and comprehensive data analysis services about the safety of treatments or components of a new drug, biologic, device, combination product or food, which often inform important marketing-related decisions. For example, Frestedt is currently evaluating and creating safety data/knowledge related to COVID-19 prevention and treatment, peptides used for brain tumor treatments and new ingredients in foods to ensure these products reach the United States (US) market. In addition, many companies currently utilize Frestedt literature search services to help understand the following types of concerns:

- How much safety data/clinical evidence is available in published literature about a particular product or component?
- What safety issues are already documented in the literature which may be related to identity, purity, quality or strength of a finished product or component?
- Are any specific claims about benefits of a finished product or component already scientifically substantiated in published literature?
- What marketability factors need consideration (e.g., to define current and potential areas of use, speed to market, etc.)?
- When is a company-sponsored trial required, advisable and helpful?

Recent safety-related projects include discussions between Frestedt and the US Food and Drug Administration (FDA) about novel treatments. FDA regulations require companies to meet specific requirements when placing products on the US market. Recently, new ventilators, face masks, hand sanitizers, wipes and gowns have been released in record time to address the COVID-19 worldwide health emergency. For example, Frestedt uses specialized forms and checklists to ensure product labeling meets FDA labeling requirements. Frestedt understands hand sanitizers and wipes containing ethanol, isopropanol and benzalkonium chloride as active pharmaceutical ingredients have different safety concerns which require different testing plans and labeling details. Frestedt is also reviewing safety information related to peptides used to treat brain tumors. This

research requires a different research approach focused on peptide safety and efficacy. Similarly, Frestedt uses a tailored research approach to identify safety concerns about new foods and dietary ingredients. Frestedt takes pride in providing services designed to advise clients about what clinical safety data has already been published and what needs more work.

Frestedt Incorporated specializes in clinical, regulatory, quality and marketing projects. If you have a project you need help with or know of anyone else needing help, please contact us (email info@frestedt.com or call 952-426-1747).

We are currently providing services in the following areas:

- Review of clinical evaluations to meet European Medical Device Regulations
- Training for Pharmaceutical engineers to improve technical writing skills
- Training about premarket authorization (PMA) for a new medical device
- Review of new FDA guidance documents such as the recent guidance about drug-drug interactions with combined oral contraceptives

If this research sounds like something you would like to pursue for employment, Frestedt is seeking additional research and sales employees (https://frestedt.com/careers-at-frestedt/).

About Frestedt Inc.

Frestedt Incorporated (www.frestedt.com) is a consulting service organization founded on February 26, 2008 to provide exquisitely targeted clinical, regulatory and quality system solutions for the pharmaceutical, medical device, biotechnology and food-related industries. We provide expertise to our clients in all stages of product development from bench, preclinical, and clinical trial services to post market research and the integration of new safety, efficacy and performance data into the developing risk management portfolio. We provide design and development leadership to research centers conducting clinical trials and regulatory submissions in order to improve the quality and cost effectiveness of the research service provided. As a result of this broad-based service approach to the industry, our clients have included some of the largest and smallest manufacturers of drugs, devices and foods in the world, as well as academic centers, Clinical Research Organizations, and clinical trial sites.

About Alimentix

Alimentix (www.Alimentix.com) is a comprehensive clinical investigation center (clinical trial site) dedicated to conducting clinical trials for foods, food ingredients, dietary supplements, natural products, over the counter pharmaceuticals and non-significant risk medical device products. We have conducted trials as diverse as weight loss and osteoarthritis, for products including calcium derived from Irish seaweed, and meal replacement beverages and we have published and presented our work both privately and within public reviewed settings.

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