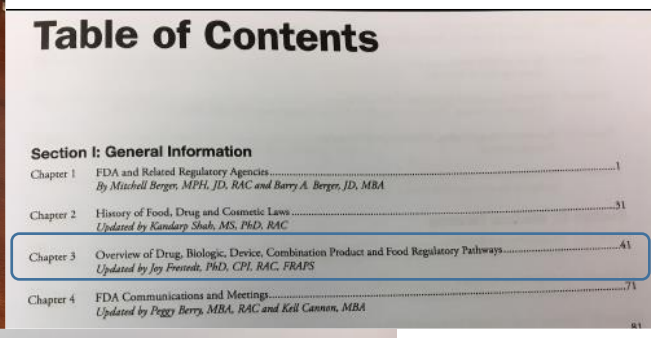
FOR THE WEBSITE - UNDER PRESS RELEASES

JULY 2017 is an Exciting Month at Frestedt Inc!

07AUG2017 ***St. Louis Park, MN*** - A lot has been happening at Frestedt Inc. and this communication is just to let you know about FIVE fun things:

1) We have a great, ever-changing team!

2) Just out TODAY: We wrote TWO chapters in the brand, new book: Fundamentals of US Regulatory Affairs, 10th Edition



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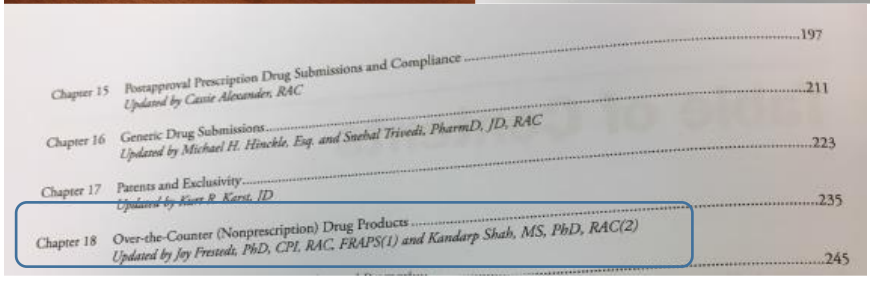

3) Also this Month: We wrote TWO articles published in peer-reviewed journals!

Food and Chemical Toxicology 105 (2017) 140–150

Contents lists available at ScienceDirect

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

GRAS from the ground up: Review of the Interim Pilot Program for GRAS notification

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ABSTRACT

After publication of the draft Generally Regarded As Safe (GRAS) rule in 1997, the United States (US) Food and Drug Administration (FDA) initiated an Interim Pilot Program encouraging the notification to FDA of GRAS determinations. This paper analyzes GRAS notifications submitted during the Interim Pilot Program along with warning letters issued during the same time period to better understand the evolution of the program and anticipate the future GRAS landscape. The success of the GRAS Notification program is demonstrated by the increasing rate of GRAS Notifications submitted to the FDA during the Interim Pilot Program, as well as the shift from a primarily domestic process to a process featuring an equal to greater contribution of GRAS Notifications from companies outside the US. Analysis of the first 600 GRAS Notifications revealed a number of interesting trends regarding the inclusion and composition of GRAS Expert Panels; differences in notifications for substances with nutritive, processing aid, or effect; and the duration of GRAS Notifications. The review of FDA warning letters associated with GRAS issues provides additional insight into GRAS notices, from the perspective of ongoing post-market emphasis on food safety with the implementation of the GRAS Final Rule.

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Austin Journal of Nutrition and Food Sciences

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Review Article

Similarities and Difference between Clinical Trials for Foods and Drugs

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Abstract

Many different types of clinical trials are designed by manufacturing companies and others to explore specific product features impacting human health. In addition, many government organizations regulate clinical trials and claims about trial findings globally, including the United States (US) Food and Drug Administration (FDA) and Federal Trade Commission (FTC) as well as the European Medicines Agency (EMA), European Food Safety Authority (EFSA) and other governments and agencies.

Food trials are often designed to evaluate specific marketing claims needing scientific substantiation while drug trials document the safety and efficacy of a specific drug for a specific intended use (e.g., to treat, mitigate or cure a human disease). Food trials tend to be more pragmatic and exploratory as they document human experiences with specific foods in the context of the human diet while drug trials tend to be more explanatory as they document specific drug doses and schedules and specific disease responses.

Food trials typically enroll healthy individuals while drug trials enroll patients with a specific disease type potentially needing the research treatment. Foods are complex mixtures of ingredients (e.g., plant parts, meats, eggs, chemicals, beverages, whole meals, etc.) designed to be palatable and which may have the general health effect under investigation while drugs are highly purified and designed to have a specific effect on a disease.

This narrative review will begin to differentiate clinical trials for foods versus those for drugs by briefly discussing the history of clinical trial designs, diversity in clinical trial regulations and the differences in specific food and drug trial requirements.

Keywords: Nutrition research; Clinical trials; Claim substantiation; FDA; EFSA

*Hanlon PR, **Frestedt JL**, Magurany K. GRAS from the ground up: Review of the Interim Pilot Program for GRAS notification. Food and Chemical Toxicology, Volume 105, July 2017, Pages 140-150. **The full article available at:** http://www.sciencedirect.com/science/article/pii/S0278691517301667?via%3Dihub*

***Frestedt JL**. Similarities and Differences between Clinical Trials for Food and Drugs. Austin Journal of Nutrition and Food Sciences. Volume 5, Issue 1, June 2017, Pages 1-8. The full article available at: http://austinpublishinggroup.com/nutrition-food-sciences/download.php?file=fulltext/ajnfs-v5-id1086.pdf*

4) We now have a CERTIFIED Internal Auditor on board!

Lindsay Young, PhD, MBA (CRQ Specialist) is now Certified by the British Standards Institute (BSI) as an ISO 9001:2015 (TPECS) Internal Auditor (as of July, 5th 2017).

5) AND we added two new staff members to our team!

Dana Goldamer (Office Manager) performs essential office management and administrative functions and assists with clinical, regulatory, quality and engineering projects. She received her Bachelor's degree from the University of Minnesota- Twin Cities in 2010.

Matthew Kerschinske (Biomedical Engineer) assists in research, design, development and implementation of concepts to advance medical products and the management of engineering and clinical concepts to support product approvals. He received his BS in Biomedical Engineering from the University of Minnesota-Institute of Technology in 2017.

Frestedt Inc is GROWING in 2017!

Rachel Anderson is helping out as a temporary CRQ Specialist and **Nitin Ajitaprasad** (a Northwestern University Biomedical Engineering student) is working with us as a summer intern.

And we are looking to add to our team!

We have two positions open for another Biomedical/Quality Engineer and a Clinical Specialist!

About Frestedt Inc:

Frestedt Incorporated is an unparalleled consortium of eight full time staff and over 70 knowledge experts working in an innovative, virtual setting to keep our service quality of the highest caliber and our costs as low as possible. The Frestedt Incorporated team works to solve problems with a forward thinking approach designed to provide all deliverables within tight timelines and budgets. We are a dynamic partner, focused on providing exactly the right solution to meet our client's needs and we hold ourselves to the highest standards in everything we do. We provide support in running clinical trials and negotiating with regulatory authorities, and we build quality systems and training sessions designed to secure the release of our client's products and claims to the market. In addition, we also provide support in creating literature reviews and clinical evidence reports for your specific needs.

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