Introduction to Spherix Consulting Group, Inc.

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A Full Complement of Services to Support the Food and Drug Industry

- **Regulatory Support**
  - Safety evaluation
  - Product approval
  - Claim evaluation and substantiation

- **Pre-Clinical/Clinical Study**
  - Design, placement, and oversight
  - Report writing and publication

- **Product Stewardship**
  - Risk assessment, management and communication
Industry Sectors We Serve

- Foods and Dietary Supplements
- Consumer Products
- Pharmaceuticals
Food Industry Services

• Foods
  ➢ Generally Recognized As Safe (GRAS)
  ➢ New Dietary Ingredient Notifications (NDIN)
  ➢ Food Additive Petitions
  ➢ Novel Food Dossier
  ➢ Health Claim and Structure/Function Claim Substantiation
  ➢ USDA Petitions

• Food Contact Substances (Notification)

• Animal Feed (GRAS Notifications, Food Additive Petitions, and AAFCO Submissions)
Our Staff Can Assist with Safety Assessments and Regulatory Submissions Worldwide

- **United States:**
  - GRAS Notifications to FDA
    (https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices):
  - GRAS Self-Determinations ➤ 80+
  - Citizen Petition (GRAS dossier for plant stanol esters)
  - USDA submissions for antimicrobial use: lauramide arginine ethyl ester (also GRAS 164) and lactoferrin (also GRAS 130)
  - Food Additive approval for glycerol ester of gum rosin (21 CFR 172.735)
  - New Dietary Ingredients: probiotics, polyphenolic extracts, sports nutrition aids, vitamins
    - NDIN# 659, 882, 993, 1062, 1104, 1143, 1250
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- **International:**
  - Food Additive submissions to Canada, European Union, Asia, Latin America, and Africa
  - Novel Food submissions and Substantial Equivalence notifications to the European Union, Canada, Australia, and Brazil
  - Natural Health Product submissions to Canada
  - Complementary Medicines submissions to Australia
  - Submission to JECFA
Diverse Product Experience

- We have experience with ingredients having complex chemistries, including:
  
  1. Complex carbohydrates and sweeteners
     - Galacto-oligosaccharides
     - Tagatose; Stevia
     - Dietary fibers
     - Isolates from *Euglena sp.*
  
  2. Lipid-containing products
     - Docosahexaenoic acid (DHA) and Arachidonic acid (ARA) (GRAS and Novel Food)
     - Emulsifiers
     - Algal oils (*Chlorella sp.*); *Euglena sp.* biomass
Diverse Product Experience (continued)

➤ Proteins
  ▪ Milk-derived proteins and fractions
  ▪ Enzymes
  ▪ Fermentation products
  ▪ Bioactive peptides
  ▪ *Euglena sp.*
  ▪ *Chlorella sp.*

➤ Prebiotics and Probiotics
  ▪ Inulin, Oligofructose
  ▪ *Bifidobacterium longum* BB536; *Bifidobacterium breve* M-16V; *Bifidobacterium infantis* M-63

➤ Botanicals and Natural Products
  ▪ Edible species-derived extracts

➤ Recombinant (Derived) Products
  ▪ Flavr-Savr tomato
  ▪ Human milk oligosaccharides
Diverse Product Experience (continued)

- **Antimicrobials**
  - Bovine milk-derived lactoferrin raw carcass spray
  - Lauramide arginine ethyl ester (LAE)
  - Global (EU, Latin America, Africa, Canada) food additive petition submissions for 4 antimicrobial products for use in beverages

- **Bacteriophages**
  - For antimicrobial use in poultry processing

- **Products for Animal Use**
  - Companion animal use (joint health)
  - Feed use in production animals (enhancing nutritional quality)
  - Veterinary medical device
    - Plug for prevention of mastitis in cows
Industry Sectors We Serve

- Foods and Dietary Supplements
- Consumer Products
- Pharmaceuticals
Consumer Products Services

- **Regulatory Review**
  - We help assess their product compliance with current and emerging scientific and regulatory guidance (FDA; EPA; Proposition 65; EU, including the 7th amendment to the cosmetic directive)

- **Product Liability Assessment**
  - We help develop a Product Stewardship program to insure appropriate guidance for sourcing of ingredients and for manufacturing of the product. We are available to help defend the safety of a product in litigation
Safety Evaluation

1. Screening for adverse health effects:
   - Potential health risks related to employee and/or consumer exposure to consumer products are evaluated.

2. Safety evaluation:
   - Unresolved issues and uncertainties in the available data are identified, and a recommendation is developed about the safety of the ingredient and the potential risk of the product during various points in its life cycle (use, misuse, disposal/recycling) is determined.

3. Analytical, pre-clinical, and clinical study support:
   - Design, placement, and monitoring of studies.
   - Results analysis and finalizing study reports.
Global Cosmetic Ingredient Services:

- Cosmetic health risk, safety and exposure assessments
- Preparation and assessment of cosmetic ingredient data
- Safety reports for ingredients including safety testing procedures, study placement and monitoring of necessary safety studies (*in vitro* and *in vivo*)
Industry Sectors We Serve

Industries

Foods and Dietary Supplements

Consumer Products

Pharmaceuticals
Pharmaceutical Industry Support

- Our scientific and regulatory consultants assist clients involved in drug development within the pharmaceutical industry with risk-based strategies
- We complete due diligence assessments in the drug development process to identify gaps in scientific and regulatory compliance
- Our extensive experience in Regulatory Submissions ensures that filings are submitted with the highest level of detail and quality
Pharmaceutical Industry Support

• **Study Design and Oversight**
  - Toxicology and Pharmacology
  - Chemistry, Manufacturing and Controls
  - Process Analytical Technologies
  - Clinical Trials (Phase I-IV)

• **Regulatory Filings**
  - Investigational New Drug Application (IND)
  - New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)
  - Combination Products
  - Drug Master Files

• **Compliance Planning and Strategy**

• **Manuscript and Report Writing**

• **Scientific and Regulatory Due Diligence Assessments in support of Merger and Acquisition**
Medical Device Industry Support

- Regulatory Filings
  - 510(k)
  - Investigational Device Exemption (IDE)
  - Premarket Approval (PMA)
- Scientific and regulatory due diligence
- Class I, II, and III devices
- Substantial equivalence determinations
- Material specifications
- Standard test methods and guides
- Biocompatibility
- Risk analysis
- FDA CDRH compliance master planning and strategy
- Quality review and design review
Further Information

For more information on our mission, values, quality, consultants, or if you would like a quote, please contact Drs. Kruger or Conze.

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