

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

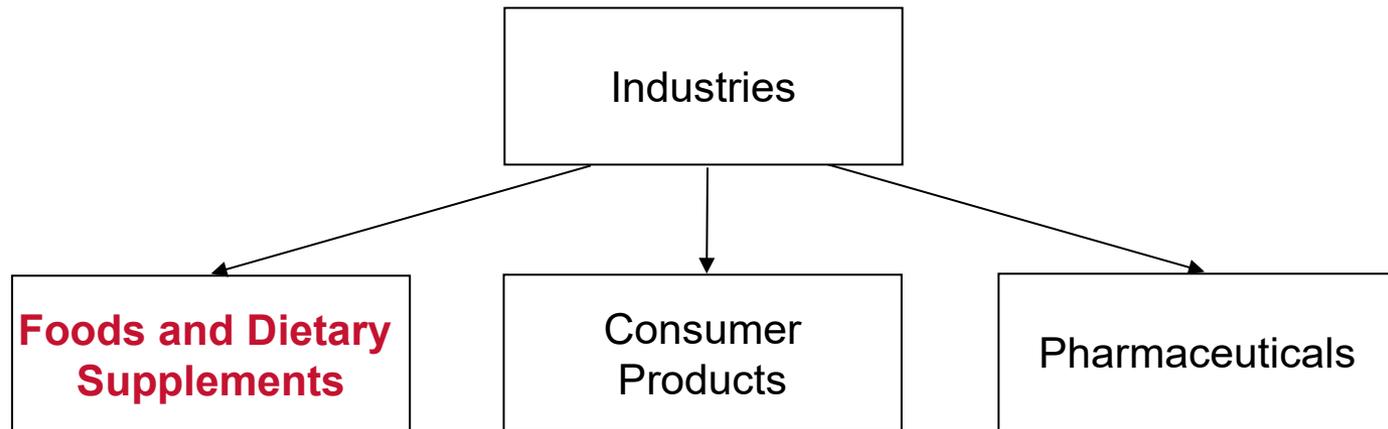
- **Pre-Clinical/Clinical Study**

- Design, placement, and oversight
- Report writing and publication

- **Product Stewardship**

- Risk assessment, management and communication

Industry Sectors We Serve



Food Industry Services

- **Foods**
 - Generally Recognized As Safe (GRAS)
 - New Dietary Ingredient Notifications (NDIN)
 - Estimated Daily Intake (EDI) Assessments using the USDA Food and Nutrient Database that provides nutrient values for foods and beverages reported in What We Eat in America, the dietary intake component of the National Health and Nutrition Examination Survey (NHANES) and DaDiet software
 - Food Additive Petitions
 - Novel Food Applications
 - 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>):

- GRN# 44, 67, 77, 78, 94, 118, 119, 130, 140, 164, 196, 233, 236, 268, 275, 326, 334, 453, 454, 455, 464, 465, 496, 576, 635, 652, 721, 800, 877, 896, 919, 921, 922, 923, 925, 934, 986, 1002, 1003, 1008, 1014, 1015, 1016, 1017, 1039, 1076, 1115, 1171, 1179, 1259

- 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, 1297

Our Staff Can Assist with Safety Assessments and Regulatory Submissions Worldwide

- **International:**

- Food Additive submissions to Canada, European Union, Asia, Latin America, and Africa
- Novel Food Applications and Substantial Equivalence Notifications to the European Union, Canada, Australia, and Brazil
- Natural Health Product submissions to Canada
- Complementary Medicines submissions to Australia
- Submissions to JECFA

Diverse Product Experience

- **We have experience with ingredients having complex chemistries, including:**
 - Complex carbohydrates and sweeteners
 - Galacto-oligosaccharides
 - Tagatose; Stevia
 - Dietary fibers
 - Isolates from *Euglena sp.*
 - 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 Products

- Flavr-Savr tomato
- Human milk oligosaccharides
- Recombinant human lactoferrin and other milk proteins

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

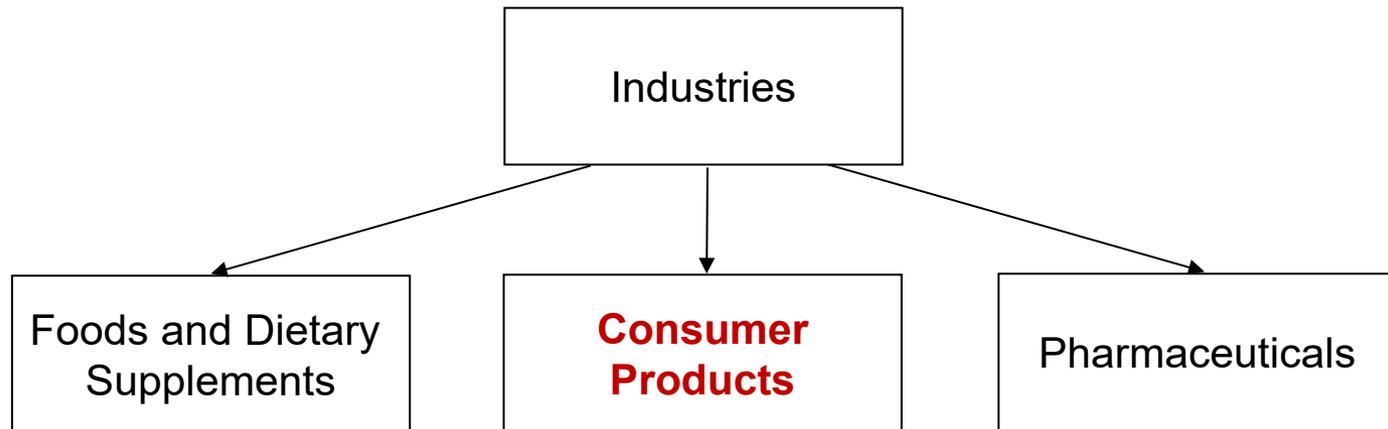
➤ Bacteriophages

- 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



Consumer Products Services

- **Regulatory Review**

- We help helps client assess their product compliance with current and emerging scientific and regulatory guidance (e.g., Proposition 65)

- **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

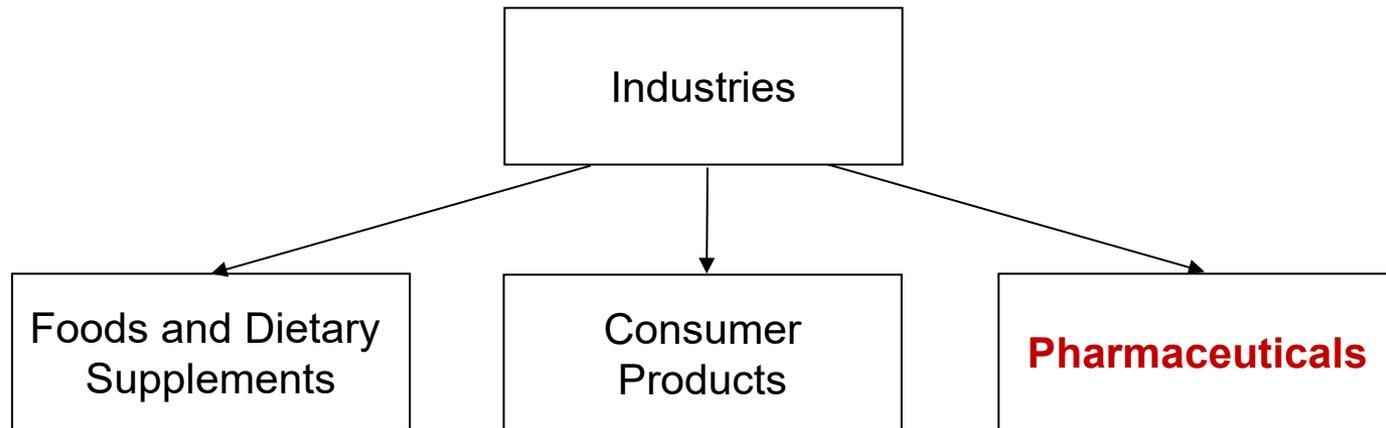
Consumer Products Services (continued)

- **Safety Evaluation**
 - Screening for adverse health effects:
 - Potential health risks related to employee and/or consumer exposure to consumer products are evaluated
 - Safety evaluation:
 - Identify unresolved issues and uncertainties in the available data
 - Recommend strategies to support the safety of the ingredient and the potential risk of the product during use
 - Analytical, pre-clinical, and clinical study support:
 - Design, placement, and monitoring of studies
 - Results analysis and finalizing study reports

Consumer Products Services (continued)

- **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



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
 - Clinical Trials (Phase I-III)
- **Regulatory Filings**
 - Investigational New Drug Application (IND)
 - Drug Master Files
- **Manuscript and Report Writing**
- **Scientific and Regulatory Due Diligence Assessments in support of Merger and Acquisition**

Medical Device Industry Support

- **Regulatory Filings**
 - 510(k)
 - Premarket Approval (PMA)
- **Scientific and regulatory due diligence**
- **Substantial equivalence determinations**

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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