Introduction to Spherix Consulting Group, Inc.

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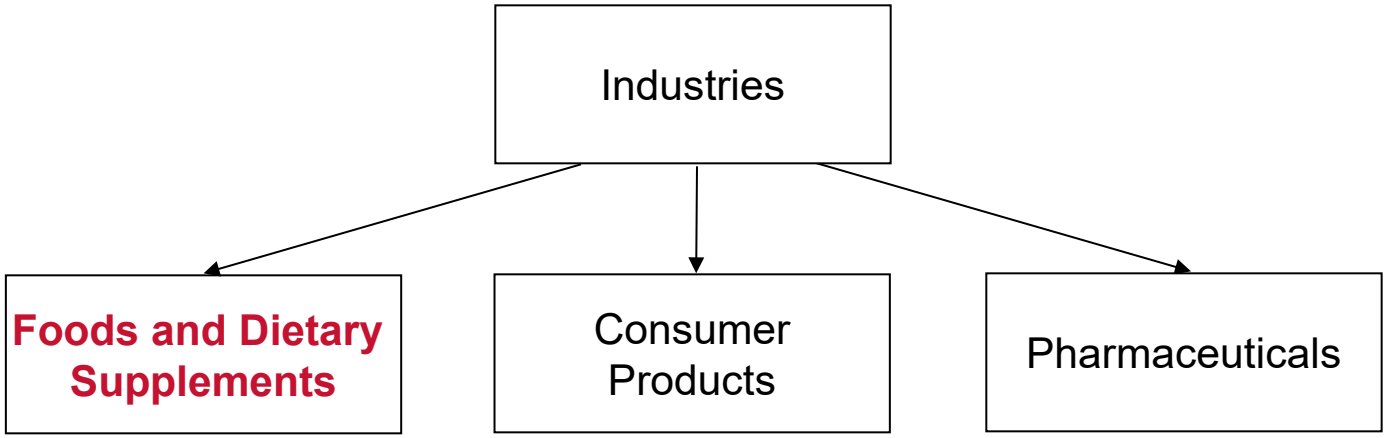
A Full Complement of Services to Support the Food and Drug Industry

- **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)
  - 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):
    - 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

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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
  - 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 (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

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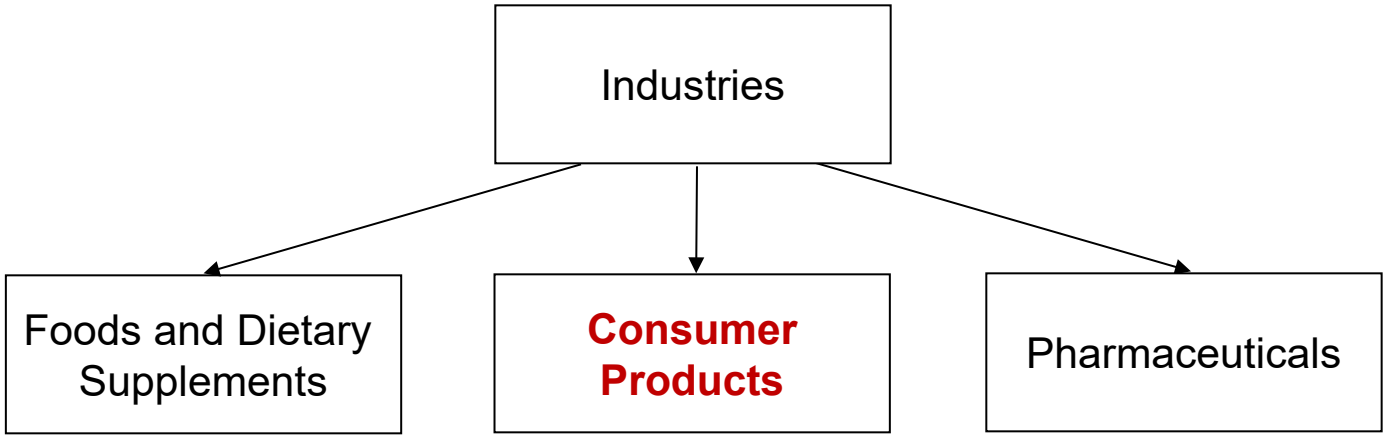

Consumer Products Services

- **Regulatory Review**
  - We help helps client 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

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:
    - 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
  - 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*)

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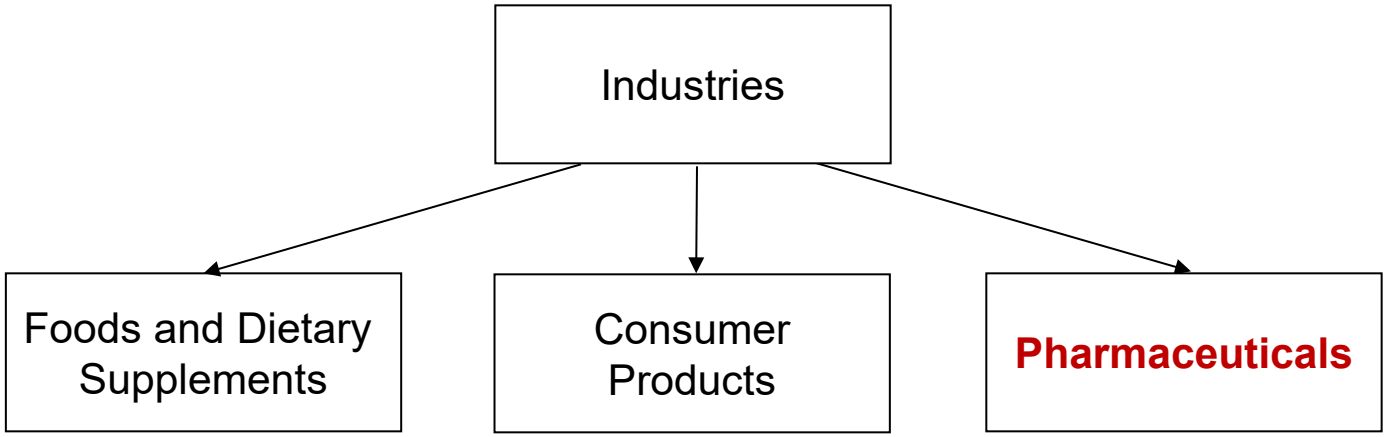

Pharmaceutical Industry Support

- **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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