Donald F. Schmitt, M.P.H., M.B.A.

SENIOR CONSULTANT

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Mr. Schmitt has more than 40 years of corporate and consulting experience in toxicology, risk assessment, and regulatory affairs. He has extensive experience in food ingredient safety assessment, food regulatory affairs, and product claims. In addition, he has broad experience evaluating the safety of additives and contaminants, feed additives, human and veterinary drugs, medical devices, cosmetics, and environmental and occupational exposures during his tenure in the drug and health-care industries. He has developed regulatory strategies for FDA-regulated products in support of regulatory compliance, product defense, product development and claims, and pre-market approval. Mr. Schmitt has conducted pre-clinical toxicity evaluations of drugs, medical devices, and biologics for both the government and private sectors. He has designed, contracted, and monitored pre-clinical safety studies required for regulatory clearance of new food additives, cosmetic ingredients, and human and veterinary drugs for clients. He has provided technical support and assisted in the preparation of a variety of reports and submissions to regulatory authorities, including Generally Recognized as Safe (GRAS) affirmation petitions, food contact notifications (FCNs), new dietary ingredient notifications (NDINs), direct and indirect food additive petitions, health claims petitions, clinical study Investigator Brochures, and Investigational New Drug and New Drug Applications (INDs/NDAs). He has experience in quality assurance programs and conduct of GLP and GCP audits.

EDUCATION AND DEGREES EARNED

1993 M.P.H., Environmental Health Sciences, The Johns Hopkins University, Baltimore, MD

1983 M.B.A., Finance, Loyola University, Chicago, IL

1976 B.A., Biology, Northwestern University, Evanston, IL

PROFESSIONAL AFFILIATIONS

Society of Toxicology

Midwest Regional Chapter of the Society of Toxicology

American College of Toxicology

Institute of Food Technologists

SCIENTIFIC PANELS

2015 NSF International Joint Committee on the Generally Recognized as Safe Publicly Available Standard

SELECTED PROJECT EXPERIENCE

Food Ingredients, Additives, and Contaminants

Managed numerous GRAS evaluations, as well as several international ingredient approvals. Prepared more than 75 GRAS assessments, which have included assessing any hazard associated with the proposed food/feed ingredient and its use in food/feed, as well as quantification of exposure from the proposed uses. Convened GRAS panels and acted as client liaison in interactions and/or submissions to FDA.

Designed, contracted, and monitored pre-clinical safety studies required for regulatory clearance of new food additives in support of GRAS evaluations. Published resultant study data in peer-reviewed journals in support of GRAS status. Conducted numerous safety/regulatory data gap analyses for ingredients proposed for use in food/feed. Identified the data/information required prior to development of a future regulatory submission (e.g., GRAS notification, FCN, NDIN).

Critically reviewed and interpreted pre-clinical toxicity data and compiled GRAS affirmation petitions, and direct and indirect food additive petitions for new food additives and uses.

Developed a GRAS affirmation petition for a product manufactured by a novel bacterial fermentation process, with proposed food use as a suspending/thickening agent. Designed, placed, and monitored (audited) pre-clinical studies required for FDA approval.

Critically reviewed the scientific database supporting proposed structure-function claims for a carbonated beverage product. The database comprised clinical, animal, and *in vitro* studies. Prepared a report reviewing the science-based strength of evidence supporting the claims using current FDA guidance.

Managed an expert panel review of scientific data supporting a proposed, qualified health claim for an infant formula product. Managed the preparation of a report reviewing the science-based strength of evidence supporting the claims using current FDA guidance.

Prepared several food contact notifications (FCNs) for rinse-aid products and managed the submission/approval process with FDA.

Critically reviewed the scientific database of a soluble fiber source traditionally used as an over-the-counter pharmaceutical agent now proposed for use as a soluble dietary fiber source in ready-to-eat cereal. The database comprised human, animal, and *in vitro* studies addressing general toxicity, vitamin and mineral absorption and availability, allergenicity, carcinogenicity, and reproductive effects. Prepared a GRAS affirmation petition in support of its safety for the proposed use.

Evaluated the safety of a chemical agent found in OTC pharmaceutical products for use as a processing aid in seafood. Reviewed the composition, manufacture, and efficacy of the agent and completed a GRAS petition incorporating an evaluation of information on its toxicity in humans and animals, and supporting its safe use in seafood.

Reviewed scientific data on an enzyme and its bacterial production strain. Prepared regulatory submissions for both food (GRAS) and drug (OTC) approvals.

Dietary Supplements

Conducted safety assessments of proposed dietary supplement ingredients and prepared appropriate regulatory dossiers, including NDINs and GRAS evaluations. Designed, contracted, and monitored pre-clinical safety studies of new dietary supplement ingredients. Published resultant study data in peer-reviewed journals in support of their safe use.

Pharmaceutical/Medical Devices

Prepared the toxicology, pharmacology, and PK/TK sections of clinical study Investigator Brochures and Investigational INDs/NDAs. One NDA was for a drug that holds promise for dramatically decreasing the high percentage of reocclusion that occurs in angioplasty patients.

Assembled several expert panels to address the safety of antimicrobial agents for use in oral hygiene products (e.g., toothpaste and oral rinse). One agent was an extract from a plant source. The evaluations included a review of the pre-clinical and clinical toxicologic database, analysis of consumer exposure, and determination of the margin of safety associated with the proposed oral uses. Several regulatory submissions, expert reports, and publications were prepared for submission to the FDA and U.K. regulatory authorities.

Reviewed the toxicologic database on acetone and assessed the exposure and associated human health risk of acetone residuals on a periodontal device.

Biotechnology Products

Prepared regulatory submissions. including GRAS evaluations, in support of products prepared by use of genetic modification/biotechnological methods (e.g. food/feed additives, plants, and dietary supplements). Assembled expert panels to address the safety of these products for their proposed uses.

PUBLICATIONS

Schmitt D, Levy R, Carroll B. 2016. Toxicological evaluation of ß-caryophyllene oil: Subchronic toxicity in rats. Int J Toxicol 35(5):558–567.

Schmitt D, Tran N, Peach J, Bauter M, Marone P. 2012. Toxicologic evaluation of DHA-rich algal oil: Genotoxicity, acute and subchronic toxicity in rats. Food Chem Toxicol 50(10):3567–3576.

Schmitt D, Tran N, Peach J, Edwards T, Greeley M. 2012. Toxicologic evaluations of DHA-rich algal oil in rats: Developmental toxicity study and 3-month dietary toxicity study with an in utero exposure phase. Food Chem Toxicol 50(11):4149–4157.

Alexander DD, **Schmitt DF**, Tran NL, Barraj LM, Cushing CA. 2010. Partially hydrolyzed 100% whey protein infant formula and atopic dermatitis risk reduction: A systematic review of the literature. Nutr Rev 68(4):232–245.

Lamb J, Hentz K, **Schmitt D**, Tran N, Junker K. 2010. A one-year oral toxicity study of sodium stearoyl lactylate (SSL) in rats. Food Chem Toxicol 48(10):2663–2669.

Schmitt D, Tran N, Riefler S, Jacoby J, Merkel D, Marone P, Naouli N. 2008. Toxicologic evaluation of modified gum acacia: Mutagenicity, acute and subchronic toxicity. Food Chem Toxicol 46(3):1048–1054.

Spiegel J, Rose R, Karabell P, Frankos V, **Schmitt D**. 1994. Safety and benefits of Fructooligosaccharides as food ingredients. Food Technol 48(1):85–89.

Frankos V, **Schmitt D**, Haws L, McEvily A, Iyengar R, Miller S, Munro I, Clydesdale F, Forbes A, Sauer R. 1991. Generally Recognized as Safe (GRAS) evaluation of 4-hexylresorcinol for use as a processing aid for prevention of Melanosis in shrimp. Regul Toxicol Pharmacol 14(2):202–212.

Schmitt D, Frankos V, Westland J, Zoetis T. 1991. Toxicologic evaluation of cellulon fiber; genotoxicity, pyrogenicity, acute and subchronic toxicity. J Am Coll Toxicol 10(5):541–554.

Greener Y, Gillies B, Wienckowski D, **Schmitt D**, Woods E, Youkilis E. 1987. Assessment of the safety of chemicals administered intravenously in the neonatal rat. Teratology 35(2):187–194.

Greener Y, Jesmok G, Grove N, **Schmitt D**, Wienckowski D, Woods E. 1985. Assessment of potential toxic effects of treated Hemofil (T-AHF) injection in rats and mice and on the systemic hemodynamics in dogs. J Toxicol Environ Health 15(6):801–811.

Greener Y, McCartney M, Jordan L, **Schmitt D**, Youkilis E. 1985. Assessment of the systemic effects, primary dermal irritation, and ocular irritation of chlorhexidine acetate solutions. J Am Coll Toxicol 4(6):309–319.

PRESENTATIONS AND ABSTRACTS

Henderson RG, Franzen A, Franke K, Payne L, **Schmitt D**, Wikoff D. Creating a literature database for cannabidiol (CBD): Systematic evidence mapping. Poster for Society of Toxicology 59th Annual Meeting, Virtual, March 2020.

Doepker D, Tyndall K, Lane R, Wikoff D, Thompson C, Harvey S, **Schmitt D**. A proposed ADI for nitrate. Poster presented at Society of Toxicology 56th Annual Meeting, Baltimore, MD, March 2017.

Alexander DD, **Schmitt D**, Tran N, Barraj L, Cushing CA. Partially hydrolyzed 100% whey infant formula and atopic dermatitis risk reduction: A systematic review of the literature. Experimental Biology, New Orleans, LA, 2009.

Schmitt D, Frankos V, Richardson D. Toxicologic evaluation of Sanguinaria extract. American College of Toxicology 11th Annual Meeting, Savannah, GA, 1990.

Youkilis E, McCartney M, **Schmitt D**, Woods E. Subchronic intravenous toxicity evaluation of Methionine-Enkephalin. Society of Toxicology 25th Annual Meeting, New Orleans, LA, 1986.