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Jim Messina

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Professional Profile

Mr. Messina has more than 30 years of experience in Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulatory affairs and strategy and specializes in pesticide product registration and support at the federal, state, and international levels. He focuses on pesticide regulations and policies under EPA for pesticide products that include conventional chemicals, biopesticides (biochemicals, plant extracts, microbials, emerging technologies) and antimicrobials. He has a strong background in EPA registration and strategic product support strategies, including an understanding of business-related strategies. He also has extensive experience with new inert (other) ingredients that are regulated by EPA under FIFRA.

Mr. Messina focuses on incorporating science, risk assessment, business needs, and regulatory compliance into developing registration strategies to obtain new active ingredient and product approvals in a timely manner. He also has experience with registration strategies for me-too or substantially-similar active ingredients and products.

Mr. Messina has extensive experience with companion animal products (dogs, cats, and horses) registered as pesticides under FIFRA. This experience includes preparing EPA registration strategies, data development (companion animal safety studies and efficacy), bridging data, preparing EPA submissions, and successful approval of EPA pesticide companion animal active ingredients and products.

He also has significant experience with new active ingredient registration of biochemicals, microbial products, and emerging technologies under EPA's Biopesticide and Pollution Prevention Division.

Mr. Messina is experienced with obtaining import tolerances for animal drugs under the Food and Drug Administration (FDA), Federal Food, Drug and Cosmetic Act (FFDCA). This work includes FDA strategies to obtain the animal drug import tolerance, data development and submission of the New Animal Drug Application (NADA).

Academic Credentials & Professional Honors

B.S., Natural Resource Management/Env Science, University of Maryland, College Park, 1992

Prior Experience

Project Manager, Novigen Sciences, Inc., 2001-2002

Senior Registration Manager, Thermo Trilogy Corporation, 1998-2001

Senior Product Manager, Jellinek, Schwartz & Connolly, Inc., 1996-1998

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Product Manager, Jellinek, Schwartz & Connolly, Inc., 1994-1995

Assistant Product Manager, Jellinek, Schwartz & Connolly, Inc., 1993-1994

Wildlife Research Assistant Volunteer, U.S. Fish & Wildlife Service, 1992-1993

Biological Technician, U.S. Department of Agriculture, 1989-1990

Professional Affiliations

U.S. Coast Guard Merchant Marine Officer, 2002-present

Publications

Messina JB. New US EPA regulatory requirements for adjuvants. Proceedings of the 9th International Symposium on Adjuvants for Agrochemicals, ISAA Society, pp. 213-220, 2010.

Presentations

Messina JB. Inert ingredient EPA regulation and the JITF history. Presentation at the Chemical Producer and Distributors Association Summer Conference and Annual Meeting, Nashville, TN, August 4, 2015.

Messina JB. New US EPA regulatory requirements for adjuvants. Presentation at the 9th International Symposium on Adjuvants for Agrochemicals, Freising, Germany, August 16, 2010.

Messina JB. The Joint Inerts Task Force (JITF), an effective task force model. Presentation at the American Chemical Society National Meeting, San Francisco, CA, March 21, 2010.

Messina JB, Daniels CL, Polakoff BM, Tucker KD. Registration? But it's a natural product. Presentation at the American Chemical Society National Meeting, New York, NY, September 9, 2003.

Project Experience

Specializes in providing EPA FIFRA regulatory support for pesticide new active ingredients, registered active ingredients, food-use and non-food use pesticide products, new end-use products, new uses of registered products, and supplemental/distributor registrations.

Experienced in supporting pesticide registrant’s efforts under EPA’s Registration Review. This includes identifying an EPA support strategy, developing data waiver requests, developing data at contract laboratories, submitting comments to the public docket and negotiating registration issues with the Agency.

Managed international registration efforts for pesticide products in Canada, Mexico, European Union, Central America, South America, Australia, and Asia.

Managed the data development for active ingredients and end-use products in support of federal and state pesticide registration, EPA registration review, EPA re-registration, special reviews, and other data requirements under FIFRA. This work includes general regulatory consulting services, coordination of client and laboratory interactions, and managing and monitoring ongoing health and safety studies at contract laboratories. His experience also includes interpretation of the data results and how the results effect the overall registration process.

Managed multiple industry task forces. He was the administrative manager for an industry task force focused on the reinstatement of tolerance exemptions for inert (other) ingredients. This work involved developing a strategic plan for each group of inert ingredients, implementing the strategy, placing and monitoring toxicology data, preparing and submitting petitions for tolerance exemption, and tracking EPA submissions to approval.

Expert in obtaining new inert (other) ingredient approvals for food-use and non-food use through EPA's Chemistry, Inerts, and Toxicology Assessment Branch. This work involved developing an EPA regulatory strategy, outlining appropriate data requirements, implementing the strategy, and preparing and submitting petitions for the new inert ingredient (including tolerance exemption petitions for food-use products).

Supported new chemical products under the Toxic Substance Control Act (TSCA), including preparing and submitting Pre-Manufacture Notices (PMNs), Low Volume Exemptions (LVEs), Polymer Exemptions, Significant New Use Notices (SNUNs), Significant New Use Rules (SNURs), Notices of Commencement of Manufacture (NOCs), Risk Assessments, and Chemical Import Issues.

Experienced in evaluating data compensation, study valuations, and cost reconstruction in support of clients' negotiations in data compensation matters.

Advised clients on regulatory and technical matters related to child-resistant packaging and required testing.

Managed reduced risk EPA petitions in support of expedited review of applications for registration for food and non-food uses. Developed the strategy and rationale to support the submission.

Performed due diligence reviews of pesticide products and supporting data for potential acquisition. Performed EPA FIFRA training for individuals and companies.

Provided regulatory and technical support for Global Review and NAFTA submissions for new active ingredients.

Prepared multiple tolerance exemption petitions for polymers (qualifying for polymer exemption), including submission of all supporting data and tracking of the EPA review and approval of the new food-use polymer inert ingredient and associated tolerance exemption.

Prepared and submitted multiple new non-food use inert (other) ingredient petitions to EPA.

Provided data compensation negotiation support for registration of pesticide product under FIFRA. Performed evaluation and valuation of data. Directed data compensation negotiations between companies.