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Jim Messina

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Professional Profile

Jim Messina is a principal scientist and director of the Chemical Regulation & Food Safety practice at Exponent. He has more than 34 years of pesticide registration support and regulatory consulting experience at the state, national, and international levels. He specializes in pesticide registration strategy, biopesticide approvals, companion animal pesticide products, and inert ingredient petitions, supporting agrochemical, animal health, and specialty chemical companies.

Mr. Messina incorporates science, data, exposure and risk assessment, business needs, and regulatory compliance into developing registration strategies to obtain new active ingredients and product approvals. He is experienced with obtaining import tolerances for animal drugs under the Food and Drug Administration's Center for Veterinary Medicine (CVM) in compliance with the Federal Food, Drug, and Cosmetic Act (FFDCA). This work includes FDA strategies to obtain animal drug import tolerances and data development. He focuses on FDA approval and maintenance of New Animal Drug Applications (NADA) and Abbreviated New Animal Drug Applications (ANADA).

Federal pesticide registration support

Mr. Messina specializes in Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulatory affairs and strategy, as well as Toxic Substances Control Act (TSCA) compliance. He focuses on pesticide regulations and policies under the Environmental Protection Agency for products that include conventional chemicals, biopesticides (biochemicals, plant extracts, microbials), and antimicrobials.

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 end-use products.

State pesticide registration support

Mr. Messina is an expert in state pesticide registration in all U.S. states with an emphasis on California, New York, Florida, Washington, Hawaii, and Arizona. He is well-versed in the intricate registration requirements specific to the noted states, including focusing on strategies to obtain concurrent or expedited review of California Department of Pesticide Regulation submissions to attempt to shorten the overall time to approval. He provides product approval support in New York, Florida, Washington, Hawaii, and Arizona, each of which has its own submission requirements that must be met to obtain product approvals.

International pesticide registration support

Mr. Messina has managed international registration efforts for pesticide products in Canada, Mexico, the European Union, Central America, South America, Australia, and Asia. He has particular expertise and experience in pesticide registration in Canada under the Pest Management Regulatory Agency (PMRA). He has prepared PMRA registration strategies and registered new active ingredients (Technical Grade Active Ingredients) and end-use products in Canada. This work included the establishment of Maximum Residue Limits (MRLs) for food use pesticides. In addition, he is experienced in obtaining generic pesticide registrations of products in Canada.

Emerging pesticide and agrochemical technologies

Mr. Messina has prepared EPA product registration strategies for new active ingredients that include unique ingredients, such as double-stranded RNA (dsRNA), peptides, proteins, and genetically modified vectors. This work included developing EPA registration strategies to comply with EPA data requirements, shepherding submissions through EPA review, and strategies to accelerate EPA review and concurrent review in California.

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

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

Federal pesticide registration support

EPA FIFRA pesticide registration

Specializes in providing EPA FIFRA regulatory strategy development 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 efforts under EPA's Registration Review, including:

- Identifying an EPA support strategy.
- Evaluating existing and new data to meet EPA guidelines.
- Developing data waiver requests.
- Developing data at contract laboratories.
- Submitting comments to the public docket.
- Negotiating registration issues with the agency.

Managed the data development for new and existing 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:

- Regulatory consulting services.
- Coordination of client and laboratory interactions.
- Managing and monitoring ongoing health and safety studies at contract laboratories.
- Interpretating data results and how the results affect the overall EPA registration process.

Managed reduced risk EPA petitions in support of expedited review of applications for registration for food and non-food uses.

Experienced in EPA registration of companion animal products. This includes successful registration of new active ingredient and generic Technical Grade Active Ingredient products and numerous end-use companion animal products.

Performed EPA FIFRA inspections, product registration reviews for EPA compliance, review of Standard Operating Procedures and provided recommendations to ensure pesticide registrants remain in compliance. Supported clients during EPA audits to ensure compliance.

Provided EPA FIFRA and State pesticide regulatory training for individuals and companies. Each training is specifically designed to meet the registrant company's needs.

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

Due diligence and data compensation

Performed due diligence reviews of pesticide products and supporting data for potential business and/or product acquisition.

Experienced in evaluating data compensation of supporting studies on-file with EPA for an active ingredient, study valuations, and cost reconstruction in support of clients' negotiations in data compensation matters related to pesticide product registration.

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

Toxic Substances Control Act (TSCA) compliance

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.

Inert Ingredient 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 and implementing EPA regulatory strategies.
- Outlining appropriate data requirements.
- Preparing and submitting petitions for the new inert ingredient (including tolerance exemption petitions for food-use products).

Prepared multiple tolerance exemption petitions for polymers (qualifying for low-risk 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, submitted, and received approval for multiple new non-food use inert (other) ingredient petitions to EPA.

Experienced in handling proprietary inert ingredient additions to EPA's Tradename Database.

FDA CVM drug approvals

Experienced in obtaining drug import tolerances under FFDCA for animal drugs via FDA Center for Veterinary Medicine (FDA CVM).

Experienced in FDA approval and maintenance of New Animal Drug Applications (NADA) and Abbreviated New Animal Drug Applications (ANADA).

Task Force Management

Managed multiple industry task forces. Mr. Messina 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.

State Pesticide Registration

Supported pesticide registration efforts in all U.S. states with an emphasis on California, New York, Florida, Washington, Hawaii, and Arizona.

- Provided registration strategy and scientific support in each noted state as the state registration requirements are more stringent to obtain individual state product approvals.
- Developed registration strategies to apply for and receive expedited or concurrent review status of pesticide product submissions in California to shorten the overall review timing.

Emerging pesticide and agrochemical technologies

Registered multiple new active ingredients in EPA's Emerging Technologies Branch that include double-stranded RNA (dsRNA), microbial active ingredients, peptides, and proteins.

- Provided strategic and scientific support for unique ingredients that are not standard active ingredients.
- Worked closely with registrants and EPA to ensure that all EPA data requirements were addressed to result in successful EPA registrations.

Developed the EPA registration strategy, supporting product-specific data and obtained the first double-stranded RNA (dsRNA) active ingredient registration with EPA.

- Support required extensive interactions with EPA to address EPA data requirements.
- Provided detailed scientific waiver requests to meet some EPA data requirements.
- Set the standard for supporting dsRNA future registrations with EPA.

Deposition & Trial Testimony

Retained as an expert witness providing EPA FIFRA regulatory testimony.