



BERGESON & CAMPBELL, P.C.

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Bergeson & Campbell, P.C.

Detailed Practice Description

This document describes in more detail the legal and regulatory advocacy services that Bergeson & Campbell, P.C. (B&C) offers.

B&C's Practice

B&C is an AV-rated (highest ranking) Washington, D.C. law firm that focuses on chemical product regulation and approval matters, including Toxic Substances Control Act (TSCA) matters, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)/Food Quality Protection Act (FQPA) matters and registration and data compensation arbitrations, chemical product litigation, medical device and product approval, and associated business counseling and litigation issues. The breadth of the firm's substantive expertise in these areas reflects the diversity of our client base, which include many small, medium, and large domestic and foreign chemical manufacturers, industry coalitions, chemical testing consortia, trade associations, medical device manufacturers, research and development testing facilities, and other manufacturing entities. B&C has extensive experience representing businesses in the basic, specialty, and agricultural and antimicrobial chemicals industry, and by far the largest percentage of our work is on behalf of the chemical industry on chemical-related matters. A copy of our firm resume is appended.

B&C is outside legal counsel to many companies with chemical products, as well as trade associations and coalitions of companies with interests in specific chemical products. These representations include, among others, coalitions of conventional industrial chemical producers and industrial chemical consortia, including the producers of acetophenone, alkanolamines, carbon disulfide, carbonyl sulfide, chelants, cresols, ethyleneamines, ethylbenzene, ethylene glycol, ethylene oxide, hydrogen sulfide, inorganics and metals, naphthalene, N-methylpyrrolidone (NMP), o-TDA, phenol, pyridine and pyridine derivatives, titanium dioxide, and many others.

We offer our clients extensive expertise in federal, state, and international requirements applicable to specific conventional chemicals, products of nanotechnology and biotechnology, and products subject to federal Food and Drug Administration (FDA) regulation. Our goal is to assist our clients in addressing proactively, or otherwise, emerging standards that will significantly affect the regulation of their products, achieving government agency approval of new products and of new uses of existing products, achieving competitive goals by making optimum use of regulatory pathways, and otherwise maintaining their products in the best possible regulatory position.



More recently, we have been engaged in the regulatory and science policy issues associated with nanotechnologies. We serve, for example, as counsel to the American Chemistry Council Nanotechnology Panel, and are actively engaged in addressing the implications under TSCA, FIFRA, and related federal laws of nanoscale materials consisting of chemical substances. More information on our nanotechnologies practice is found below.

TSCA Experience

B&C has substantial experience in assisting clients on a wide array of issues arising under TSCA, including the regulation of products of biotechnology. B&C is a long standing sponsor of the American Chemistry Council/Synthetic Organic Chemical Manufacturers Association Global Chemical Regulations Conference. All of our attorneys have considerable experience in assisting clients with TSCA regulatory and litigation matters. In addition, many of our attorneys and other professionals have scientific and regulatory backgrounds that make them uniquely qualified to address the science-based legal issues that arise under TSCA.

We are especially pleased that Jim Aidala, former U.S. Environmental Protection Agency (EPA) Assistant Administrator for Toxics under the Clinton Administration, is on our team. Jim has a technical background, having attended Brown University, Harvard, and MIT before joining the government. Jim has been intimately involved with TSCA legislative reauthorization and key regulatory matters for over two decades, and offers significant value in addressing chemical policy and related issues.

Dr. Joseph Plamondon, who has a Ph.D. in organic chemistry from the University of California at Davis, brings a unique perspective to TSCA issues, as he has spent over 25 years as part of the regulated community at the Rohm and Haas Company and Akzo Nobel. Dr. Plamondon has had a long and distinguished career, and is well known in the industrial chemical community. In addition to his work within the chemical industry, he has spent over ten years consulting with chemical companies on a broad range of TSCA issues. These have included providing strategic preparation and submission of premanufacture notifications (PMN) designed to avoid TSCA Section 5(e) consent orders and other adverse regulations, as well as offering guidance to companies in the determination of whether certain health and safety information is reportable under TSCA Section 8(e). Dr. Plamondon has presented at many conferences and professional meetings, *e.g.*, the American Chemistry Council's Global Chemical Regulations Conference (Living with TSCA), among others, and has written extensively on chemical regulatory matters.



Additionally, Susan Hunter Youngren, who has a Ph.D. in environmental biology, has more than 18 years of experience in the field of risk assessment, with particular emphasis on exposure assessment. She has served as the project manager/senior scientist for a diverse range of risk assessments required under FIFRA, including residential, dietary, and microbial exposure assessments; under Proposition 65, including Maximum Allowable Dose Level (MADL) and No Significant Risk Level (NSRL) development; and under the Resource Conservation and Recovery Act (RCRA), including Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)/RCRA hazardous waste site assessment. Dr. Youngren is well versed in the preparation of individual, aggregate, and cumulative residential and consumer product exposure assessments using deterministic and Monte Carlo techniques. Dr. Youngren has managed and conducted numerous residential and occupational exposure assessments and is well suited to assist clients before EPA when exposure issues are raised in the context of PMN reviews.

B&C's TSCA experience includes:

- TSCA compliance audits, assessing compliance with all TSCA provisions;
- Section 4 test rules and related Organization for Economic Cooperation and Development (OECD), EPA, and Interagency Testing Committee (ITC) testing issues;
- High Production Volume (HPV) Chemical Challenge Program, Extended HPV Program, and International Council of Chemical Associations (ICCA) testing, including testing coalition formation and representation;
- Voluntary Children's Chemical Evaluation Program (VCCEP);
- Section 8(a), (d), and (e) recordkeeping and reporting requirements, Standard Operating Procedures (SOP), and systems development issues;
- PMN/Microbial Commercial Activity Notice (MCAN) requirements;
- PMN requirements pertinent to products of nanotechnology and engineered nanoscale materials;
- Section 5 Significant New Use Rules (SNUR);
- Section 6 chemical restrictions, including bans;



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- Export issues;
- Inventory issues;
- Polychlorinated biphenyl (PCB) issues;
- Approval and regulation of nanotechnology products and biotechnology products; and
- Defense advocacy.

We also often work closely with clients on ensuring that their facilities have the expertise and tools necessary to avoid TSCA compliance problems. We prepare TSCA compliance manuals and SOPs and regularly conduct in-house training seminars for clients.

In addition, we work on many chemical-specific issues that cut across EPA programs. For example, we are now representing manufacturers of several chemicals in connection with EPA's notices announcing the Integrated Risk Information System (IRIS) review of certain chemicals. Both cancer and non-cancer endpoints are being assessed.

Nanotechnologies Practice

B&C works with its individual and trade association clients on emerging nanotechnologies issues, many of which are relevant to, or dependent for their resolution on, nomenclature and terminology. Lynn Bergeson served on the Steering Committee of the American National Standards Institute (ANSI) Nanotechnology Standards Panel and now is a member of the U.S. TAG for the ISO/TC 229 Nanotechnologies Standard, and serves on the Board of Directors of the Converging Technologies Bar Association and is Chair of its Environment, Health and Safety Committee. Lynn also serves as counsel to the American Chemistry Council Nanotechnology Panel, which consists of companies engaged in various applications of nanotechnologies and/or engineered nanoscale materials.

Issues that we are often asked to explore involve assessing the opportunities for exposure to engineered nanoparticles in occupational settings, assisting in the characterization of risk, and assessing the potential application of existing chemical regulatory laws and regulations to engineered nanoscale materials and nanostructures to ensure legal compliance and effective risk communication. These issues arise in the context of how products of nanotechnologies fit within the existing regulatory framework governing the production and importation of industrial chemicals and/or products (industrial and consumer) containing these chemicals and potential human and environmental exposure to them. Examples include:



- ***TSCA*** -- whether an existing Inventory listing includes a nanoscale material, or whether it is a new chemical substance, and the resulting regulatory issues flowing from those determinations.
- ***Clean Air Act (CAA)*** -- particulate matter issues (coarse/fine/ultrafine) and issues pertaining to emissions generated by fuel additives using micro particles of atypical metals that are added to diesel fuel for on road use under CAA Section 211.
- ***RCRA*** -- whether conventional waste disposal practices are adequate to protect against the release of engineered nanoscale materials into the environment.
- ***Workplace Standards*** -- as they might govern, for example, potential respiratory irritation posed by nanotechnologies products manufacturing.
- ***Workplace Hazard Communication*** -- including labeling, notification, and material safety data sheet (MSDS) preparation.
- ***Food Safety and Related Food Packaging Approval Issues.***

Medical Device Approval Issues.

FIFRA Experience

B&C has substantial experience in FIFRA regulatory and business matters. B&C works closely with our consulting affiliates, The Acta Group, L.L.C. (Acta) and The Acta Group EU, Ltd (Acta EU), on product registration issues. Both B&C and Acta represent large, medium, and small agricultural chemical and non-agricultural biocide producers on a broad range of FIFRA regulatory compliance and data compensation issues, and related business issues. In addition, we represent several pesticide producer task forces and are thoroughly familiar with the legal and business issues that arise in such coalitions. More information on Acta is noted below.

We have substantial experience in the developing law, regulation, and policy of antimicrobial products. We routinely counsel companies on how best to promote their antimicrobial products in ways that maximize marketing opportunities without running afoul of the often shifting regulatory requirements imposed by EPA and FDA. In this regard, we have assisted many clients in addressing legal issues affecting product marketing under EPA's



reinterpretation of the treated article exemption from pesticide regulation and in obtaining EPA approval of expanded claims for their products.

We routinely advise clients on a full range of FIFRA issues. Other areas in which we practice include:

- FQPA implementation issues;
- Data compensation rights;
- Experimental use permits (EUP);
- Tolerance revocation, maintenance, and establishment proceedings, including those relating to import tolerances;
- Reregistration Eligibility Decision (RED) documents;
- Cancer and related risk issues;
- EPA/FDA dual jurisdiction issues;
- Section 25(b) matters;
- Pesticide Registration Improvement Act (PRIA) matters;
- Biochemical and microbial pesticides;
- FIFRA enforcement policy issues;
- Section 6(a)(2) notice requirements;
- Supplemental registrations;
- The formulators' exemption;
- Data requirements;
- Reregistration;
- Joint data development agreements;



- FIFRA compliance obligations;
- Task force agreements; and
- California registration regulations.

Additionally, B&C attorneys have substantial experience in representing basic data owners and follow-on, generic registrants in addressing all aspects of FIFRA data compensation matters. We assist clients in developing strategies to minimize data compensation, and represent clients in data compensation negotiations and arbitration proceedings.

B&C represented a data owner in its successful effort to recover data compensation in an arbitration proceeding that involved landmark issues for data owners. Our client prevailed on the major issues on which a data owner must carry its burden of proof. The arbitrators found that our client's actual external costs of conducting the studies were accurate and allocated internal management costs equal to those that our client claimed. In addition, the Panel awarded our client its claimed adjustment of the costs to reflect the cost of capital calculated at the prime rate of interest. The Panel allocated these costs between the parties on an equal sharing basis, with some modest adjustment for the time required for the Respondents to become an equal competitor in the marketplace. Moreover, the Panel awarded our client a significant "risk premium" for the commercial and regulatory risks that it assumed in developing its data.

We have substantial experience in defending products in proceedings that involve, for example, Notices of Intent to Suspend, cancellations, and special reviews, among others. In addition, we have worked on many FIFRA enforcement matters, which have involved labeling, export/import, EUPs, and other issues. This work has included related negotiations of supplemental environmental projects (SEP) included in enforcement agreements.

Endocrine Experience

We routinely conduct advocacy on behalf of many clients on endocrine disruptor issues. EPA published for public comment the approach it plans to use for selecting the first group of chemicals to be screened in the Endocrine Disruptor Screening Program (EDSP). Based on the Science Advisory Board (SAB)/Scientific Advisory Panel (SAP) recommendations, EPA is proposing to select and screen approximately 50 to 100 chemicals drawn from pesticide active ingredients and HPV chemicals with some pesticidal inert uses (HPV/inert chemicals) to help further refine the EDSP. EPA intends to submit the data received from the screening to an independent external panel of experts and request an evaluation of whether the program could be



improved or optimized, and if so, how. It is essential that chemical producers, as well as manufacturers of products that contain chemicals believed to pose endocrine effects, monitor and participate in these global initiatives.

Air Experience

B&C assists clients with a host of different, but complementary, federal CAA and state air law issues, as well as litigation concerning air issues. Our significant representation of general and specialty chemical producers has enabled us to work closely with toxicologists, biostatisticians, and epidemiologists in other, more specialized areas of air regulation. These include the following:

- On behalf of six chemical consortia, we are working to persuade EPA's Air and Toxics Offices to reconsider their decision to propose a TSCA Section 4 test rule for hazardous air pollutants (HAP), which applies to the chemicals that each of these consortia addresses. We are also working with several of these consortia to negotiate enforceable consent agreements (ECA) in response to the proposed rule.
- We are working with fuel additive manufacturers to ensure their products are registered in accordance with CAA Section 211. This effort has involved the resolution of technical issues for the Tier 1 testing required for fuel additive manufacturer notifications, and legal issues pertaining to the obligation to update registration materials when slight changes are made to the registered additive. We have also assisted with data generation issues that often arise in connection with Section 211 registration issues.
- We have commented on many rulemaking proposals and other EPA initiatives under CAA Section 112, including Section 112(r) (accidental releases), 112(g) (modifications), and 112(i)(5) (early reduction) for various coalitions of organic and inorganic chemical producers. We have also advised clients on a variety of matters relating to the listing and delisting of chemical substances and the delisting of source categories under Section 112.
- We routinely render advice for clients on prevention of significant deterioration (PSD) regulations and federal regulations aimed at protecting the stratospheric ozone layer.



- We routinely counsel clients in the development of National Emissions Standards for Hazardous Air Pollutants (NESHAP).

B&C additionally represents businesses on a full range of Title V issues. We also routinely represent clients in enforcement proceedings arising under federal and state air laws.

EPCRA Experience

B&C has extensive experience in counseling clients on regulatory and enforcement matters under the Emergency Planning and Community Right-to-Know Act (EPCRA). B&C's representations have included the following projects:

- B&C has prepared several petitions to delist chemicals from the EPCRA Section 313 toxic chemicals list and has assisted clients in conducting advocacy efforts relating to other pending delisting petitions.
- B&C has worked with many clients in defending EPCRA enforcement actions. These actions have addressed issues such as the definition of an "article" and the alleged failure of industrial entities to file required Form R reporting reports.

RCRA/CERCLA Experience

B&C has significant experience in all aspects of the federal RCRA and CERCLA programs. Under RCRA, we routinely counsel clients on waste classification issues and newer aspects of the RCRA program, including the land disposal restrictions and corrective action programs. With respect to waste classification issues, for example, B&C counseled the Dithiocarbamate Task Force, which won its challenge to the carbamate listing rule before the United States Court of Appeals for the District of Columbia Circuit. The appeal raised novel questions relating to EPA's then newly announced waste listing determination policy. B&C assisted the Task Force in persuading the court to vacate 28 out of 29 waste listing determinations based on the court's conclusion that EPA failed to satisfy the Administrative Procedure Act. *Dithiocarbamate Task Force v. EPA*, 98 F.3d 1394 (D.C. Cir. 1996).

We also counsel a host of clients on state RCRA analog programs, including those in California, New York, New Jersey, Florida, and many other states. Because RCRA is a mature program, we do not further detail here the many types of RCRA issues in which B&C has experience. We would be pleased, however, to respond to any questions in this regard that you may have.



B&C's CERCLA experience is similarly substantial. B&C routinely serves as counsel to clients across the nation with regard to their liability at CERCLA sites and their disputes with the government and other potentially responsible parties relating to those sites. B&C also coordinates CERCLA litigation conducted by local firms for a number of its clients that have ongoing CERCLA matters in many different states.

Water Experience

B&C has extensive experience in Clean Water Act (CWA) and Safe Drinking Water Act (SDWA) matters, both in the counseling and enforcement areas. Like the RCRA program, the CWA/SDWA programs are mature and we do not detail here our experience with these matters, but would be pleased to do so upon your request.

NTP Experience

B&C has significant experience in counseling clients and conducting advocacy initiatives with the National Toxicology Program (NTP). B&C represents a number of companies and trade organizations that have disputed, or are in the process of disputing, the findings of an NTP study. Our assistance in this regard has consisted of marshaling the technical resources necessary to launch a full-scale attack of the findings, drafting the advocacy documents necessary to support such an effort, and representing our clients in discussions with NTP staff. All too often chemical manufacturers and producers of products sold to the public are unaware of NTP's research initiatives involving critical compounds and the effects that adverse cancer bioassays have on the marketability of chemicals that are the subject of NTP review.

We work closely with companies and chemical testing consortia to ensure that NTP's selection of chemicals, protocols used once a chemical has been nominated for chemical testing, and the technical conclusions and inferences drawn from the test results are presented in a fair and technically defensible way. B&C offers clients an NTP tracking system that advises clients of the status of NTP's chemical testing initiatives with respect to particular chemical compounds. This tracking system allows companies an opportunity proactively to participate in the chemical testing process. Doing so helps blunt the possibility for erroneous test results, and hence minimizes the possibility that ill-conceived conclusions will be drawn with respect to test chemicals.

One notable success in this area relates to the NTP Board of Scientific Counselors' *Report on Carcinogens* Subcommittee 2002 decision that diethanolamine (DEA) not be added to the 11th *Report on Carcinogens*. B&C assisted the manufacturers of DEA in their advocacy before NTP, and will continue to assist in this regulatory process, which is expected to conclude this year.



Another of our successes in this regard relates to the International Agency for Research on Cancer's (IARC) decision to classify pyridine as a Group 3 carcinogen (not classifiable as to a chemical's carcinogenicity to humans). Our representation of the major U.S. manufacturer of pyridine over the past few years involved challenging the findings of the draft NTP technical report on pyridine, which concluded that, among other things, there was clear evidence of carcinogenic activity of pyridine in mice. Our advocacy efforts contributed to IARC's ability to classify pyridine as a Group 3 chemical, as opposed to a B2 carcinogen, which would have inspired significant adverse implications for the global regulatory status of pyridine, as well as products in which it is included.

We also assist clients on NTP matters before the Center for the Evaluation of Risks to Human Reproduction (CERHR). We represented the producers of ethylene glycol in the NTP-CERHR Expert Panel review of ethylene glycol in February 2003. The CERHR has since determined that ethylene glycol was of "minimal concern" by NTP-CERHR for human reproduction and developmental toxicity.

Occupational Safety and Health Experience

B&C routinely counsels clients on a wide variety of matters under the Occupational Safety and Health Act (OSH Act). B&C's representations have included the following projects:

- B&C is assisting manufacturers of titanium dioxide (pigment grade) with developing the National Institute for Occupational Safety and Health (NIOSH) *Comprehensive Intelligence Bulletin (CIB) on Titanium Dioxide*. B&C is also working with other clients in identifying Occupational and Safety Workplace practices intended to mitigate potential risks posed by engineered nanoscale materials and occupational settings.
- B&C is assisting or has assisted several chemical consortia in the development of American Conference on Governmental Industrial Hygienists' threshold limit values (TLV) applicable to, among other chemicals, carbon disulfide, hydrogen sulfide, phenol, ethylene glycol, and certain nickel compounds.
- We have assisted the producers of DEA and triethanolamine (TEA), chemicals found in metalworking/machining fluids, in the Occupational Safety and Health Administration's (OSHA) review of the permissible exposure limit (PEL) for oil mists. We are also assisting the producers of



DEA and TEA in challenging NTP's findings with respect to DEA's and TEA's carcinogenicity, as both OSHA and NIOSH are relying upon these findings in reviewing the PEL.

- B&C assisted the producers/users of carbon disulfide in challenging the final air contaminant standard (PEL) for carbon disulfide promulgated in 1989. We are assisting the producers of several chemical manufacturers in addressing the PEL update initiative.
- B&C is defending or has defended companies in enforcement actions brought by federal and state OSHA offices, including, among others, Alabama, California, Maryland, New York, Indiana, and Tennessee. These actions have been based on allegations of noncompliance with, among other provisions, health and safety standards, the general duty clause, and Section 11(c) (whistle blower provision).

FDA Experience

We represent a variety of medical and chemical companies that develop and market products regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA).

- We assist companies in bringing food contact substances and food packaging materials to market. We provide advice regarding the possible pathways to marketing without the requirement of a filing to the Center for Food Safety and Applied Nutrition (CFSAN), and if those avenues are not open, we assist with the preparation and prosecution of Food Contact Notifications. In that regard, we arrange and participate in pre-submission conferences intended to refine and limit data requirements. We review draft notifications for sufficiency, and we assist with the answers to questions posed by CFSAN.
- We consult with companies and individuals regarding the steps necessary to bring medical devices to market, and how to manage the difficult issue of the regulation of drug-device combination products. As with the food packaging practice, we assist in picking the appropriate pathway to approval or concurrence to market, review draft submissions, and help move them through the channels at the Center for Devices and Radiological Health (CDRH).



- We also represent clients in many types of compliance proceedings involving the FFDCFA. B&C helps resolve disputes during factory inspections and helps prepare responses to Warning Letters and letters alleging violations regarding promotion, particularly claims of promoting off label uses. We meet with the compliance officers at all the Centers to resolve compliance issues, and assist clients in designing and implementing corrective action plans to resolve outstanding compliance issues.
- We advise clients on cosmetic issues, including:
 - Preparation, review, and defense of label and advertising claims;
 - Defend cosmetic ingredient use in challenges involving the toxicological properties of chemical substances used as ingredients; and
 - Counseling clients on all matters involving enforcement and compliance sensitivities.

We additionally assist many clients in navigating the often murky jurisdictional divide between EPA and FDA concerning chemicals used in one or more pesticidal, food additive, and medical device applications, particularly with regard to the regulation of antimicrobial claims.

International Experience

In addition to traditional environmental counseling, B&C has developed a strong international practice. In addition to representing foreign entities with U.S. regulatory matters, our consulting affiliate, Acta, opened an office in Manchester, U.K., Acta EU, in 2004. Acta EU is actively engaged in product registration matters in the European Union (EU) and elsewhere. B&C is actively involved in monitoring and advocacy activities before the regulating bodies formed under the United Nations Environmental Programme (UNEP), agencies of EU member states, and the OECD, and is closely following Registration, Evaluation and Authorization of CHemicals (REACH) issues. B&C is prepared to offer a variety of services relating to REACH, which is now expected to Enter Into Force (EIF) in early 2007. These services will include providing up-to-date information regarding the rapidly changing REACH implementation plan, responding to company specific issues, and acting as the “Only Representative” in Europe for companies that do not have a legal entity in EU countries.



China represents another international venue of increasing importance to companies wishing to do business there. B&C's consulting affiliates, Acta and Acta EU, recently entered into a strategic alliance with Life Plus, LLC (Life Plus), a consulting facility located at Purdue Technology Center. Life Plus offers unique expertise in Chinese chemical registration matters and access to testing facilities located in China. This affiliation enables Acta to offer unique services that enable us to assess whether a particular chemical substance or mixture must be registered in China, and, if so, how to accomplish the registration. We also have significant abilities to access in China modern testing laboratories, which not only meet Chinese requirements, but which provide alternative Good Laboratory Practice testing at a competitive cost for other purposes such as those required under REACH.

B&C also has considerable expertise with Canada's New Substance Notification (NSN) regulations, including major changes implemented in the past year (October 2005). The Canadian system is somewhat different than that of the U.S. under TSCA, and understanding these subtle differences is critical in order to conduct effectively business there.

B&C counsels clients on legal issues arising in connection with the formation of international joint ventures formed to test the toxicology of chemicals, particularly in the pesticide and biocide areas. Our work has required us to become familiar with other countries' regulatory agencies and registration requirements. Our consulting affiliate, Acta EU, offers more robust regulatory services in the U.K. and EU.

B&C's Consulting Affiliate
The Acta Group, L.L.C. and The Acta Group EU, Ltd

B&C's consulting affiliates, Acta and Acta EU, were established to control the spiraling costs and inefficiencies encountered by clients seeking approvals to market chemicals and medical products. Acta manages products from concept to approval, utilizing the skills and experience of professionals who have worked in the specific product areas in government and industry. Acta represents the following disciplines: regulatory affairs, toxicologists, and government affairs. Acta professionals have experience in regulations affecting chemical product approvals under North American (USA, Canada, and Mexico), EU, South American, Asian, and Pacific Rim regulatory programs. They regularly track significant legislative, administrative, and scientific initiatives that relate to the business of clients marketing chemicals and medical products for multiple uses.

The experience and expertise of Acta professionals cover a wide range of chemicals and products, including pesticides; industrial and specialty chemicals regulated under TSCA; and medical devices. Acta concentrates on obtaining and maintaining product approvals and overcoming impediments to the successful and profitable marketing of approved products.



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The multi-disciplinary skills possessed by members of Acta are essential to a cost-effective and timely product approval project. Today's regulatory approvals hinge on the utilization of multiple sources of information, resources, and skills. Acta offers a complete line of services intended to take a product or product concept to the point of its commercial marketing, to protect the market position of new and existing products, and to maintain products once they have been approved.

Attachment

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