



## The Acta Group, L.L.C.

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### The Acta Group, L.L.C.'s

#### FDA Practice

This document is intended to introduce you to The Acta Group, L.L.C.'s (Acta) diverse food, drug, and cosmetic practice. The Food and Drug Administration (FDA) regulates medical devices and diagnostics, cosmetics, and human prescription and over-the-counter drugs. FDA regulation extends to a variety of products, from food additives and food contact substances to animal drugs and biologics. Acta professionals are familiar with the regulatory requirements of each of these product categories. The specific requirements for meeting FDA obligations vary from product to product, but the basic practice typically involves one or more steps in a sequence of interactions with FDA.

Acta business and scientific professionals assist clients with strategic planning, counseling on the regulatory requirements applicable to client product lines, and developing pathways to expedite approval of marketing applications. Our professionals accompany clients to meetings with FDA regarding submissions, and help prosecute the approval of the applications when filed. After approval, Acta professionals assist clients in planning and implementing marketing programs consistent with the approvals obtained.

We routinely engage in regulatory matters arising under the Federal Food, Drug, and Cosmetic Act. Many of Acta's business and scientific professionals are highly skilled in various aspects of chemical and product-specific regulatory activities in addition to matters under FDA's jurisdiction, including the complex jurisdictional issues invited by the joint regulation of certain antimicrobials by the U.S. Environmental Protection Agency (EPA) and FDA. Our extensive pesticide practice makes Acta uniquely suited to address these and related matters efficiently and well.

Acta professionals routinely assist clients in a wide range of food regulatory matters, including:

- ***Materials Used in Food Packaging*** -- A rapidly escalating part of the practice is representing the producers of materials used in some phase of the assembly of food packaging materials. Manufacturers of end-use products are becoming increasingly insistent that everything used in the manufacture of food packaging materials be approved or otherwise sanctioned for use, and that the supplier of the intermediate be able to produce evidence of that fact. Acta business and scientific professionals

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help inform what regulatory form a needed approval should take, whether it is through a food additive petition, the newer, more streamlined Food Contact Notification process, obtaining agreement from FDA's Center for Food Safety and Nutrition that the use of the substance meets the Threshold of Regulation exemption requirements, or claiming that the use of the product makes it a substance that is Generally Recognized As Safe. Acta professionals will help the producer select the most efficient and appropriate regulatory pathway.

Once a course of action is selected, Acta scientific professionals will help the producer of the substance prepare the necessary application, and the business and scientific professionals will help the producer work the application through FDA.

- ***Materials Used in Applications Making Contact with Food Surfaces*** -- This is an area of great interest, particularly when the substance in question is a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulated antimicrobial being added to the product in question as a materials preservative. Such an application raises thorny questions of FDA/EPA jurisdiction, and the extensive experience of B&C legal professionals in dealing with FIFRA issues before EPA is available to augment the FDA professionals in addressing these matters efficiently and effectively.
- ***Antimicrobials Added to Drug or Device Products*** -- Acta's multidisciplinary team of experts is well versed in dealing with approval and/or registration issues, concerns about the possibility of antimicrobial resistance, and the affect that issue may have on approvals.

Acta professionals are also highly experienced in the area of medical device matters. Michael Cole has significant experience in this area, and has procured FDA approval for hundreds of medical devices. We assist clients in a wide range of areas, including:

- Counseling on the need to submit and the strategy for obtaining clearances for device Premarket Notifications and Premarket Approval Applications;
- Preparing Drug Master Files;



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- Counseling on medical device classification matters; and
- Defending medical device products before FDA in all compliance matters, including product recall, FDA inspection practices, and related compliance and enforcement sensitivities.

Acta often partners with its legal affiliate, Bergeson & Campbell, P.C. (B&C). B&C professionals bring legal expertise to strategic planning, product approvals, and advocacy. Acta business and scientific professionals, and B&C legal professionals, are expert in developing approval applications, moving them along through the approval process, and managing the process efficiently when jurisdictional issues involving EPA and FDA arise. For more information on B&C's capabilities and professionals, please visit <http://www.lawbc.com>

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