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BERGESON & CAMPBELL, P.C.

FDA Practice

This document is intended to introduce you to Bergeson & Campbell, P.C.'s (B&C) diverse food, drug, and cosmetic practice. The jurisdiction of the Food and Drug Administration (FDA) extends to a wide variety of professional and consumer products in the areas of food and food additives, medical devices, *in vitro* diagnostics, cosmetics, human prescription and over-the-counter drugs, and animal drugs and biologics. B&C professionals are familiar with the regulatory requirements for all of these products.

The Practice in General

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. The first step is the consideration of the appropriate regulatory pathway to consider. With the exception of cosmetics, all of the above described product areas involve some form of approval, concurrence to market, compliance with standards or monographs usually contained in regulations, or qualification for a stated exception from the need for clearance.

B&C legal 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 will advise on the preparation of submissions, accompany clients to meetings with various offices within FDA regarding submissions, and help prosecute the approval of the applications when filed. After approval, B&C professionals assist clients in planning and implementing marketing programs consistent with the approvals obtained. Our professionals also assist with the design and implementation of manufacturing and quality assurance procedures necessary for most products regulated by FDA, and provide clients with guidance on the requirements for importing and exporting regulated products.

B&C professionals also assist clients with compliance matters that may arise after a product is in distribution. Such matters commonly involve advertising or promotional claims and product labeling. A company may be alleged to be promoting a product for uses outside the approval obtained from FDA, or it may be alleged to be making claims unsupported by valid scientific evidence. Other compliance matters may relate to allegations of failure to follow quality systems requirements or good manufacturing regulations, or a failure properly to follow-up and/or report adverse events claimed to be related to a product. A company may also come

under scrutiny for making changes to a product that FDA contends a new approval or concurrence is necessary prior to marketing.

Specialized Practice Areas

FDA-EPA Jurisdictional Questions

Many of B&C's legal and scientific professionals are highly skilled in various aspects of chemical and product-specific regulatory and enforcement-related 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. The most difficult of these issues include the following:

- ***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*** -- B&C'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 this and other thorny issues may have on approvals.

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. B&C legal and scientific professionals help inform what regulatory pathway a needed approval should take. The substance might not need to be registered because there is no migration from the packaging to food. A Food Additive Petition or the newer, more streamlined Food Contact Notification might need to be filed. It

might be necessary to obtain agreement from FDA's Center for Food Safety and Applied Nutrition that the use of the substance meets the Threshold of Regulation exemption requirements. Finally, it might require a manufacturer determination, with or without FDA consideration, that the substance qualifies as GRAS, a substance "generally recognized as safe." B&C professionals will help the producer select the most efficient and appropriate regulatory pathway.

Once a course of action is selected, B&C scientific professionals will help the producer of the substance design any protocols needed for migration studies or toxicological tests, help assemble the necessary chemical and related technical information, combine this information into the necessary application, and help the producer work the application through FDA.

Medical Devices

B&C professionals are also highly experienced in the area of medical device law. We assist clients in a wide range of areas, including:

- Determination of the regulatory status of the proposed product, and whether it is exempt from filing, and if not, what type of Premarket Notification might be required. More difficult questions arise when the proposed product requires a Premarket Approval Application or is a drug-device combination subject to special requirements.

- Preparation of the necessary application when one is required, including showing proof of compliance with applicable standards and inclusion of material outlined in guidance documents.

- Following the application through the system, assisting the client in responding to questions raised by reviewers and organizing and attending meetings to discus application issues.

- Compliance with the Quality Systems Regulation, and the requirements applicable to promotion, with a focus on issues relating to alleged off label use. B&C professionals also work with clients on complaint handling and reporting procedures, a topic of great interest to FDA in the device field.

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

B&C often partners with its consulting affiliates, The Acta Group, L.L.C. (Acta) and The Acta Group EU, Ltd (Acta EU). Acta and Acta EU professionals bring technical and business expertise to strategic planning, product approvals, and advocacy. B&C business and legal professionals and Acta and Acta EU scientific 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 Acta and Acta EU capabilities and professionals, please visit http://www.actagroup.com.

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