Karl M. Nobert

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Industries

Agribusiness
Life Sciences

Practices

FDA Regulatory
Regulatory

Overview

Karl focuses his practice in FDA Regulatory law, representing U.S. and international clients in the food and drug industries with regard to pharmaceuticals and OTC drugs, biologics, medical devices, food and beverages including dairy products, cosmetics, vitamins and dietary supplements, and veterinary products.

He has particular experience in the areas of prescription drugs and regenerative medicine, and has counseled numerous clients seeking FDA approval for Rx drugs and cellular-based products to treat both humans and animals.

Experience

Karl helps clients navigate the complex FDA regulatory process including assistance with:

- Preparing and filing FDA submissions for both innovator and generic drugs, and shepherding applications through the approval process
- Evaluating legal questions involving marketed unapproved drugs including pre-1938 grandfathered drugs, the DESI program, and the application of the Weiss List
- Reviewing OTC drug labeling and promotional materials for FDA compliance and potential regulatory risk
- Preparing and filing 510(k) medical device premarket notifications and premarket approval applications
- Assist contact lenses manufacturers and sellers with issues related to the PMA approval process, the cGMP requirements of the Quality System Regulation / QSR (21 CFR Part 820), pharmacovigilance or adverse event reporting, labeling and marketing, and evaluation of risk for purposes of conducting a market withdrawal or recall.
- Strategies to overcome prescription drug approval delays
- Advising on product labeling, packaging, and cGMP manufacturing requirements
- Product listings and establishment regulations
- Responding to FDA warning letters

- Preparing clients for FDA and USDA facility inspections
- Conducting due diligence reviews prior to sales and acquisitions
- Resolving product seizures by U.S. Customs and obtaining removal from import alert list
- Product recalls and market withdrawals involving both FDA and USDA regulated products such as Rx drugs, foods, meats, and dairy products.
- GRAS self-affirmations and notifications
- Reviewing advertising and marketing content for compliance with FTC regulations
- State food and drug regulatory matters including wholesaler/distributor licensing and registration

In addition to FDA matters, Karl has represented companies before the U.S. Department of Agriculture (USDA), the Federal Trade Commission (FTC), the National Advertising Division of the Better Business Bureau (NAD), the Association of American Feed Control Officials (AAFCO), and the Alcohol and Tobacco Tax and Trade Bureau (TTB).

Before joining Michael Best, Karl was Chairman and CEO of ReCellerate, Inc., an emerging veterinary pharmaceutical company that develops cell-based drug products. In this role he directed efforts in cultivating and vetting cell-based therapeutics, oversaw the FDA approval process, crafted and managed the company's regulatory strategy, and helped secure funding to grow the business.

During his tenure with ReCellerate, Karl also established the Nobert Group LLC, where he practiced FDA regulatory law. He previously spent nearly 10 years in private practice, all focused in the FDA Regulatory field.

Professional Activities

- Member, American Bar Association

Education

- Villanova University School of Law, Juris Doctor (J.D.), 2002
- Villanova University School of Business, Master of Business Administration (M.B.A.), 2002; Concentrations in Finance and Marketing
- University of North Carolina at Chapel Hill, Bachelor of Arts (B.A.), 1997; History

Admissions

- Connecticut
- District of Columbia
- New York

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