Theodore M. Sullivan

Partner

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Theodore M. Sullivan counsels and advises clients on Food and Drug Administration (FDA) regulations and matters related to prescription and over-the-counter pharmaceuticals, medical devices, biological products, cosmetics, and foods and dietary supplements.

In the pharmaceutical area, Theodore has experience in both pre- and post-approval matters. He has advised clients in bringing their products to market and in developing product life-cycle extension strategies. He has worked on a variety of compliance matters, including manufacturing and clinical site inspections, import detentions, and Warning Letter responses. He has extensive knowledge of the citizen petition and notice of opportunity for hearing processes. He is experienced with both human and veterinary drug products.

Theodore has worked extensively with medical device companies including experience with premarket approval and premarket notification (510(k)) submissions. Device experience includes work with traditional medical devices as well as software devices and in-vitro diagnostic tests.

Before joining the firm, Theodore was legal counsel for an international medical device company, where he worked to launch the company's subsidiary in the United States, obtained pre-market approval for injectable medical devices, and advised the company on FDA-related advertising, labeling, import/export, clinical, and manufacturing issues. Before practicing law, Theodore was an FDA biologist at FDA's National Center for Food Safety and Technology, where he conducted research into methods for detection of food-borne pathogens and toxins.

Legal Services

- Health & Life Sciences
  - FDA Regulatory Practice
  - Wholesale Drug and Device Distribution

Education and Honors

- Chicago-Kent College of Law (J.D., *with honors*, 1997)
- George Mason University (B.S., 1989)
  - Degree: Biological Sciences

Bar Admissions

- District of Columbia