Wayne H. Matelski

COUNSEL

Wayne is a leading attorney in the Food & Drug practice and is the firm's senior pharmaceutical and medical device attorney.



Industries

Fashion & Retail Law
Health Care
Life Sciences

Practices

Food, Drug, Medical Device & Cosmetic
Pro Bono

International

Asia
China
Europe

Education

The George Washington University, JD, with honors, 1974

The Pennsylvania State University, MA, With Highest Distinction, 1974

The Pennsylvania State University, BA, With Distinction, 1970

Offices
Los Angeles
Washington, DC

Phone
202.857.6340

Email
wayne.matelski@afslaw.com

Wayne Matelski is a leading attorney in ArentFox Schiff's Food and Drug Practice and is the firm's senior pharmaceutical and medical device attorney. Wayne concentrates his practice in the area of food and drug and controlled substance law, advising clients on their obligations and rights under the laws and regulations of the federal Food and Drug Administration, the Drug Enforcement Administration, and various related federal and state agencies.

Client Work

Wayne's work involves the representation of clients in the pharmaceutical, medical device, controlled substance, chemical, food, dietary supplement, and cosmetic industries.

He represents such clients on product development, preparing Investigational and New Drug Applications (INDs, NDAs, and ANDAs) and Investigational Device Exemptions (IDEs); Biologics License Applications (BLAs); medical device Premarket Approval Applications (PMAs) and 510 (k) Notifications; facilitating the entry of imported products through Customs; counseling on, and reviewing manufacturing plants for, compliance with good manufacturing and good laboratory practices; evaluating labeling and advertising claims; and defending against various types of enforcement actions taken by the government.

In the FDA pharmaceutical and medical device areas, Wayne's representative client work has included the following:

- The preparation of an NDA for the first new dental anesthetic drug approved by the FDA in the last 20 years
- Preparation of numerous NDA Supplements including, among other things, changing the manufacturing site for a drug, changing a drug's packaging configuration, changing a drug's container closure system, changing aspects of a stability program for a drug, and changing a drug's specifications to meet the established USP and NF Monographs
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Meetings with FDA officials and planning strategy on INDs, NDAs, and PMAs

- Preparation of ANDAs and ANDA Supplements for a wide variety of generic pharmaceutical products
- Preparation of Annual and Periodic Reports for both NDA and ANDA products and for Drug Mater Files (DMFs)
- Preparation of Citizen Petitions to be submitted to the FDA
- Advising clients on Hatch-Waxman issues involved with Paragraph (iv) certifications and acting as food and drug counsel in patent infringement cases involving drugs subject to the Hatch-Waxman rules
- Counseling clients on numerous advertising issues involved with prescription drugs – including pre-approval and direct-to-consumer advertising - and drafting complaint letters to the FDA on competitive products
- Preparation of Risk Management Plans and negotiating with FDA over the contents of such plans
- Conducting regulatory, due diligence, and current Good Manufacturing Practice (cGMP) audits of both domestic and foreign manufacturing and distribution pharmaceutical and medical device facilities
- Responding to Warning and Untitled Letters received from the FDA
- Conducting audits of continuing medical education (CME) and medical liaison programs for pharmaceutical and medical device companies
- Advising clients on their need to comply with state requirements, including Florida (and other state) pedigree rules, California Proposition 65 and compliance program statutes, etc.
- Advising medical device clients on the need for filing PMAs and PMA Supplements, and preparing such PMAs and PMA Supplements
- Preparation of numerous 510(k) Notifications for a wide variety of medical devices
- Advising clients on the need for filing Radiation Control for Health and Safety annual and periodic reports
- Counseling clients on enforcement actions (both administrative and criminal) brought under the food and drug laws
- Coordinating drug, device, and food recalls, market withdrawals, and other product corrective actions, and negotiating with the FDA over the terms and conditions of such actions
- Advising clients on debarment requirements, and defending debarment actions brought by the FDA

In the DEA area, Wayne has been counsel to a company that obtained approval of an application to import controlled substances (one of only four companies presently allowed to import such substances). This involved a multi-week administrative hearing before a DEA Administrative Law Judge and the subsequent successful defense of an appeal to the US Court of Appeals for the District of Columbia Circuit.

In addition, Wayne advises his DEA clients on a wide variety of DEA regulatory issues, including quotas, security and employee screening controls, drug diversion, company and physician enforcement matters, etc.

Wayne recently served as an expert witness for the Australian government in an enforcement action in Australia brought against a purveyor of internet prescription drugs. He also served as an expert witness in an arbitration involving a contractual dispute over an interpretation of whether a company exercised due diligence in pursuing approval of an NDA. The company for which Wayne was the sole expert witness was subsequently awarded all the damages it had requested, along with full attorneys' fees, costs, and interest.

Outside of the food and drug field, Wayne has led and participated in general civil litigation matters, particularly in the area of defamation law and immigration class actions.

Previous Work

Following law school, Wayne served as a law clerk for two years to Judge J. Walter Yeagley of the DC Court of Appeals. Upon completion of his clerkship, he joined a small Washington, DC food and

drug law firm, which merged with ArentFox Schiff in 1983.

Professional Activities

Wayne is one of the leading partners in the pro bono program at ArentFox Schiff and has served on the firm’s Pro Bono Committee for over 20 years.

Bar Admissions

District of Columbia