Natasha Leskovsek

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Natasha Leskovsek advises pharmaceutical, biotechnology, medical device and food/dietary supplement industry clients on US Food and Drug Administration regulatory and clinical development matters. She also conducts regulatory diligence on behalf of entities investing in FDA-regulated companies.

Before entering legal practice, Natasha worked as a registered nurse in pediatric oncology research at the National Institutes of Health and with adult medical and surgical patients. She worked as a consultant for international pharmaceutical and biotech clients while attending Georgetown University Law Center. Her direct clinical trial experience in nursing and project management offers her a unique perspective in advising clients on the conduct of clinical trials in product development and post-marketing studies. She has authored numerous healthcare and FDA-related publications and regularly speaks on a broad range of FDA regulatory topics for national conferences and meetings.

Recent engagements:

- Development of product approval and lifecycle management strategies for prescription and OTC drugs, medical devices and biologics.
- Counseling on clinical trial issues, including clinical trial agreements, master service agreements, informed consent terms, reporting of AEs and clinical hold issues.
- Preparation of orphan designation requests.
- Preparation of sponsors for face-to-face meetings with FDA and participation at FDA meetings to ensure that client rights are preserved.
- Advise on compliance strategies for federal and state regulatory matters, including advertising and promotional materials, labeling review, records retention and state permitting requirements.
- Development and drafting of comments to FDA proposed rules and Citizen Petitions.
- Draft and review FDA regulatory representations, warranties and milestones in licenses and other transactional documents.
- Conduct FDA regulatory due diligence and provide opinions on same for venture capital and public financing, both as corporate and underwriter's counsel.
- Coordinate with patent counsel on patent term restoration requests and Hatch-Waxman Act litigation.
- Respond to FDA inspection reports and warning letters, as well as preparing clients for inspections and audits.

Education

Georgetown University Law Center
JD , 1996

University of Maryland, College Park
MBA , 1991

University of Maryland, College Park
MPM , 1991

University of Maryland, Baltimore
BSN ,1989

Admissions & Credentials

District of Columbia

Maryland

Memberships & Affiliations

Food and Drug Law Institute