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Life Sciences and Healthcare Regulatory
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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