Hogan Lovells

# Gary L. Veron

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## Biography

For more than 20 years, Gary Veron has advised clients regarding the development, approval, and marketing of pharmaceutical and biological products. Gary is committed to helping life science companies successfully manage legal and business complexities to achieve their goals. His practice focuses on Hatch-Waxman Act, biosimilars, and life cycle management issues.

With a degree in biology and prior experience as a registered patent attorney, Gary understands how the science fits in the legal framework. In particular, he has considerable experience handling issues that occur at the intersection of FDA and intellectual property laws. He draws on his unique background to counsel clients regarding comprehensive development strategies, including market exclusivity periods, *Orange Book* issues, and therapeutic equivalence determinations. Gary assists clients in resolving the novel issues raised in biosimilar and 505(b)(2) applications.

Gary also has experience negotiating technology transfer and license agreements and managing patent prosecution matters. Before joining Hogan Lovells, Gary practiced both food and drug law and patent law at another international law firm. His experience includes serving as a Technology Development Specialist at the National Institutes of Health (NIH), where he was the

## Practices

Pharmaceuticals and Biotechnology Regulatory

Administrative and Public Law

Intellectual Property

## Industries

Life Sciences and Health Care

intellectual property manager for four NIH institutes.

Gary's experience and skills have earned recognition in the *Best Lawyers in America* (FDA Law) and *Legal 500 USA*.

## Representative experience

Citizen petition regarding issues raised by a 505(b)(2) application for a palonosetron product that differed from the reference product.

Citizen petition regarding labeling carve-out and orphan drug exclusivity issues related to generic bendamustine products.

Citizen petition regarding the approval standards for a 505(b)(2) application for a bortezomib product.

Citizen petition regarding three-year exclusivity, labeling carve-out, and 505(b)(2) issues related to generic colchicine.

Citizen petition regarding safety and orphan drug exclusivity issues raised by an Abbreviated New Drug Application (ANDA) for generic thalidomide.

Citizen petition regarding reference drug and patent certification issues raised by a 505(b)(2) application for an extended-release oxycodone product.

Comments to a draft bioequivalence guidance regarding bioequivalence issues related to complex products that are not fully characterized.

Comments to a suitability petition seeking approval for different strengths of the reference product.

## Awards and rankings

- FDA Law, *The Best Lawyers in America*, 2016-2019
- Healthcare: Life Sciences, *Legal 500 US*, 2014

## Latest thinking and events

## Areas of focus

Pharmaceuticals and Biotechnology

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Cell, Tissue, and Gene Therapies

## Education and admissions

### Education

J.D., University of Virginia School of Law, 1993

B.S., Virginia Polytechnic Institute and State University, cum laude, 1990

## Bar admissions and qualifications

District of Columbia

Maryland

U.S. Patent and Trademark Office

## Court admissions

U.S. Court of Appeals, District of Columbia Circuit

U.S. Court of Appeals, Federal Circuit

U.S. District Court, District of Columbia

U.S. District Court, District of Maryland

- Insights
  - “Misleading” to suggest a biosimilar is inferior, FDA draft guidance warns
- Insights
  - FDA issues draft guidance regarding “sameness” for Orphan Drug gene therapies
- Insights
  - Spending bill advances FDA biosimilars policy
- Hogan Lovells Publications
  - FDA to consider patent listing, therapeutic equivalence, and other Orange Book issues; agency will issue draft guidance documents, seek public comment *Focus On Regulation*
- News
  - FDA mulls Orange Book overhaul to address patent listing, therapeutic equivalence, other issues
- News
  - Four new FDA guidances and proposed rule advance biosimilars policy framework