

Edgar J. Asebey

Partner

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Edgar J. Asebey is a life sciences regulatory and transactional attorney with over 20 years of experience advising pharmaceutical, biotechnology, biologics, medical device, food, and dietary supplement companies on FDA compliance and related regulatory matters, including licensing, transactions, and venture finance.

Edgar represents clients before the U.S. Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), U.S. Customs and Border Protection (CBP), the U.S. Federal Trade Commission (FTC), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety & Health (NIOSH), and the Drug Enforcement Agency (DEA). His work includes providing compliance and enforcement defense services before these agencies. He assists companies with FDA registration, clearance, and pre-market approval, and advises on compliance throughout the development, manufacturing, marketing, and sale of FDA-regulated products.

Edgar also conducts regulatory due diligence to support venture financings, public offerings, and M&A transactions, and advises emerging life sciences and psychedelic drug development companies on patent strategy, FDA regulatory pathways, and clinical trial planning. Since 2016, he has counseled cannabis and hemp businesses, providing regulatory, transactional, and due diligence services to hemp/CBD, cannabis/marijuana, and psychedelics biotechnology companies.

In addition to his legal practice, Edgar is a founding member and the FDA regulatory advisor to the Iter Investments Fund, a venture capital firm focused on supporting emerging psychedelic biotech companies.

Earlier in his career, Edgar was Patent and Licensing Advisor to the Natural Products Branch of the National Cancer Institute (NCI) at the National Institutes of Health (NIH), later founding and leading Andes Pharmaceuticals, Inc., a natural products biotech company. He has served as in-house counsel to two life sciences companies, was an equity partner in a AM 200 law firm's Health Care & Life Sciences Practice Group, and in 2016 founded Keller Asebey Life Science Law, PLLC, the predecessor to Asebey Life Science Law.

Education

Catholic University of America, Columbus School of Law, J.D.

- Concentration: Patent Law

University of Illinois, Abraham Lincoln School of Medicine, M.D. Candidate

The University of Chicago, B.A.

- Concentration: Molecular Biology

Admissions

- District of Columbia
- Florida

Edgar has an extensive record of thought leadership, with more than 50 published articles, reports, book chapters, and books, and has delivered over 60 presentations at seminars, webinars, and conferences across the U.S., Europe, Latin America, Japan, and India.

Edgar is fluent in Spanish.

Professional Affiliations

- **American Bar Association**
  - *Section on Administrative Law & Regulatory Practice, Committee on Food & Drug*
    - Member 2009-Present
  - *Health Law Section*
    - Member 2016-Present
- **Food & Drug Law Institute (FDLI)**
  - Member 2005-Present
- **Dade County Bar Association**
  - Member 2009- Present
- **BioFlorida**
  - Member 2006-Present
- **Iter Investments, LLC**
  - Member, Advisor 2021 – Present
- **Psilera Inc.**
  - Advisor 2021 – Present

Experience

- Advised stem cell company on Florida's new stem cell therapies law and associated FDA regulatory compliance matters
- Advised GLP-1/peptide businesses on FDA and FTC regulatory compliance
- Represented GLP-1/peptide companies in FDA enforcement actions
- Provided clinical trial and FDA regulatory advisory services to U.S.

biopharmaceutical venture developing psilocybin-derived therapeutics for various mental health indications

- Assisted a psychedelics biotech company in preparing for a pre-IND meeting with the FDA, guiding them through the FDA regulatory process
- Provided counsel to global medical device company on U.S. portion of a global Class II recall, creation and implementation of a CAPA, and on mitigation of possible consumer and class action litigation
- Led regulatory due diligence and advised Cardinal Health, Inc. on FDA regulatory requirements in connection with a $240M acquisition of a clinical decision support (CDS) software company
- Advised fortune 500 company on FDA and FSMA regulatory compliance matters associated with the acquisition of an Australian food company
- Responded to FDA Warning Letters and 483s on behalf of dietary supplement, food, and medical device clients, ensuring FDA compliance
- Counseled German distributer and Italian manufacturer of medical devices regarding 510(k) submission to FDA, removal from FDA Import Alert, CGMP compliance, and the close-out of an FDA Warning Letter
- Advised a Brazilian biologics company on the §351(k) pathway for licensing a biosimilar as well as on FDA regulatory compliance
- Provided regulatory compliance services to a $2.4 billion hospital group on FDA and state healthcare laws governing the commercialization of de-identified human solid and liquid tissue
- Advised and negotiated on behalf of a European API manufacturer a $94 million IP licensing and supply agreement with a prominent U.S. medical foods company
- Advised various hemp companies on state and federal regulatory matters related to the manufacture, marketing and distribution of Delta-8 THC-containing products
- Represented South American Cannabis/hemp company in acquiring biomass and extraction/distillation equipment from distressed U.S. hemp/CBD venture
- Provided crisis management services, supervised implementation of corrective and preventive action (CAPA) plan, and interfaced with FDA in a self-disclosure of Quality System deficiencies of a U.S. company's Class III medical device
- Provided FDA regulatory guidance to various Health IT and medical mobile app companies with regard to product registration & clearance and FTC advertising compliance matters
- Successfully removed a major Chilean salmon company from an FDA Import Alert, demonstrating in-depth experience navigating FDA regulatory processes
- Represented beverage, dietary supplement and cosmetics companies in California Prop 65 actions, navigating complex state and federal compliance issues
- Assisted a Danish company in creating a dossier for a New Dietary Ingredient

Notification (NDIN) submission to the FDA

- Negotiated and drafted licensing, purchase, and distribution agreements for various food companies in the U.S., Japan, and Latin America, with a focus on FDA regulatory compliance
- Managed food recalls for dietary supplement, human, and pet food companies, in close coordination with FDA
- Performed label, advertising, and social media review for cannabinoid, Kava, and Kratom-containing beverages, ensuring FDA compliance and adherence to FTC advertising requirements
- Advised French women's health pharmaceutical company HRA Pharma on FDA regulatory compliance and due diligence matters in connection to the company's sale to Goldman Sachs and Astorg Partners, a private equity firm, by The Riverside Company
- Advised a U.S. biopharmaceutical company on the potential sale of option rights to a pediatric priority review voucher (PRV)
- Performed regulatory and IP due diligence on various psychedelic biotech ventures on behalf of a U.S. venture capital fund
- Negotiated an IP licensing agreement and sponsored research agreement between a biotech client company and Brigham and Women's Hospital/Harvard University

Awards & Recognition

- Dean's Scholarship for Biomedical Research, 1987-88, Abraham Lincoln School of Medicine, University of Illinois
- Edmundson-Garber Scholarship for Undergraduate Research, (1985), The College, The University of Chicago

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