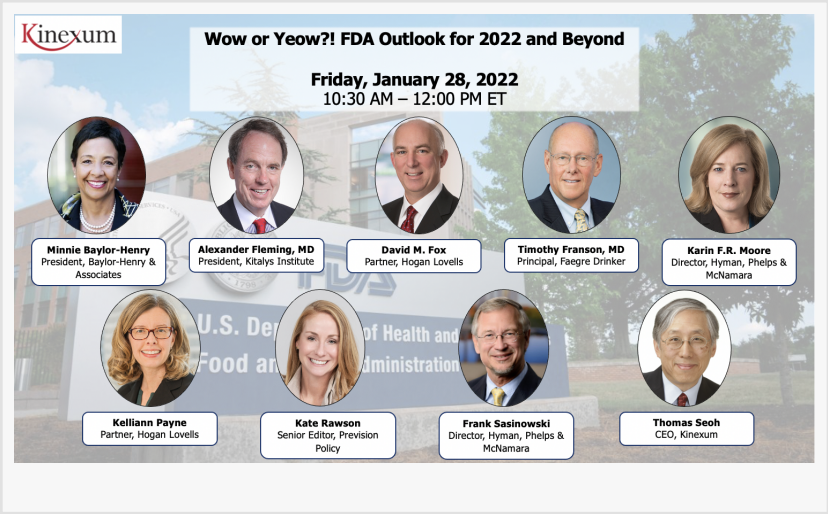
5th Annual “Wow! Or Yeow?!: FDA Outlook for 2022 and Beyond” FREE Webinar

All Star panel will hold a wide-ranging discussion and entertain audience questions on Friday, January 28, 2022, from 10:30 am to 12:15 pm EST.



UNITED STATES, January 25, 2022 /EINPresswire.com/ -- The “Wow! or Yeow?!” webinar was first held on Inauguration Day, January 20, 2017, to discuss whether the outlook for drug development in the coming year might be amazing (Wow!) or unexpectedly painful (Yeow?!). Join us on January 28, 2022 from 10:30 am to 12:15 pm EST for the 5th edition, as an all-star panel reviews FDA developments from the past year and looks ahead to the next. No longer focusing just on drugs, the panel will survey the entire FDA landscape—ranging from devices, digital technology, and vaccines to nutritional products. With FDA in the news daily, everyone in the life sciences can benefit from the packed session, which will include a “Lightening Round” and audience Q&A.

PLEASE CLICK HERE* TO REGISTER FOR FREE.

Registrants will automatically receive a link to the webinar recording when it is released.

Topics include:
- 2021 Year in Review at FDA CDER, CBER, CDRH and CFSAN
- Incoming FDA Commissioner Watch
- Impact of COVID (on clinical trials, manufacturing inspections, transition out of pandemic)
- Aduhelm Fall-Out (Accelerated Approvals, Advisory Committees, other products under review)
- Are Ex-US Data Sufficient for Approvals? (e.g., in light of the wave of oncology applications based on clinical data from China)
- Are the Floodgates Opening for Cell Therapies? But Are Gene Therapies Stuck?
- Orphan Watch (including the Catalyst case which extends orphan designation to a disease, not just the labeled indication, and FDA’s wait for a Congressional ‘fix’)
- CDRH Device Watch (e.g., Genus Medical case that reclassified drugs and device;

software/AI/Predetermined Change Control Plans; trends in de novo grants and drug-device combination products)
• CFSAN Watch (CBD, Bioengineered (BE) food disclosures, Generally Regarded As Safe (GRAS) developments)

Panelists:

Minnie V. Baylor-Henry, Esq. is President of Baylor-Henry Associates, and formerly Worldwide VP for Regulatory Affairs, Johnson & Johnson Medical Devices & Diagnostics; VP for Global Regulatory Affairs OTC at McNeil Consumer Healthcare, a J&J company; and Senior Director of Pharmaceutical Research & Development. Ms. Baylor-Henry is former director of the Drug Marketing, Advertising, and Communications division of the US FDA. She also served as President of the Drug Information Association and of the Food and Drug Law Institute. Ms. Baylor-Henry received a pharmacy degree from Howard University's College of Pharmacy and a law degree from Catholic University's Columbus School of Law.

Alexander Fleming, MD is Founder and Executive Chairman of Kinexum, a strategic advisory firm specializing in regulatory, clinical, CMC, and other translational aspects of life science product development. During his tenure at FDA, Dr. Fleming led reviews of landmark approvals, including metformin and the first statin, insulin analog, PPAR-agonist, and growth hormone for non-GH deficiency indications. He also helped to shape FDA policies and practices related to therapeutic review and regulatory communication. Dr. Fleming is also founder and President of the not-for-profit 501(c)(3) tax exempt Kitalys Institute, whose mission is to accelerate the translation of emerging advances in the biology of aging into public health, the prevention of chronic diseases and the extension of healthy longevity for all.

David M. Fox, a Partner at Hogan Lovells, and formerly an Associate Chief Counsel for drugs at FDA, advises management teams from start-ups to the largest global pharmaceutical and biotechnology companies on matters before the FDA and DEA. Mr. Fox previously led Hogan Lovells' Pharmaceutical and Biotechnology practice group and now serves on the firm's global Life Sciences management team.

Timothy Franson, MD currently serves as a Principal at Faegre Drinker. He was formerly VP of Global Regulatory Affairs at Eli Lilly and Company, where he was directly responsible for the company's FDA submissions (NDAs and supplements), which involved more than 20 major submission reviews and approvals.

Karin F.R. Moore is a Director at Hyman, Phelps & McNamara, PC in Washington, DC. She was formerly General Counsel to the Grocery Manufacturers Association (now Consumer Brands Association), Ms. Moore counsels on a broad range of FDA and antitrust regulatory, policy and compliance matters, with a focus on food and beverage products. Ms. Moore is an active member of the ABA Section of Antitrust Law and is an editor of the forthcoming edition of the ABA's ANTITRUST AND ASSOCIATIONS HANDBOOK.

Kelliann Payne, a Partner at Hogan Lovells, drafts premarket submissions for diagnostic and therapeutic medical devices, evaluates and formulates applicable regulatory strategies, and reviews the accuracy of marketing claims. In her role as Assistant General Counsel at QVC, Inc. from 2013 to 2014, Ms. Payne counselled internal clients on FDA and FTC regulations applicable to health, wellness, beauty, and cosmetic products.

Kate Rawson is a senior editor at Prevision Policy LLC, a continuous information service based in Washington, DC. She has more than 25 years of experience covering FDA-regulated health care industries, primarily pharmaceuticals and biotechnology. Kate co-founded the annual FDA/CMS Summit for Biopharmaceutical Executives and the Biopharma Congress. Both are annual conferences in Washington, DC. Previously, she helped launch and was a senior editor for “The Pink Sheet” DAILY, and served as Managing Editor of “The Rose Sheet,” which covers regulatory and business news of the cosmetics industry.

Frank Sasinowski , a Director of Hyman, Phelps & McNamara, has helped secure FDA approval for hundreds of new drugs, including more than 100 new molecular entities, often for serious and rare diseases. Mr. Sasinowski has been involved in many of the recent drugs FDA approved by way of its accelerated approval process. He is involved in many cell and gene therapies and aided significantly on the first approved systemic gene therapy, Zolgensma. Mr. Sasinowski joined FDA in 1983 as regulatory counsel in the Center for Drugs and Biologics, where he was key to implementing both the 1983 Orphan Drug law and the 1984 Hatch-Waxman law.

Thomas Seoh is President and CEO of Kinexum, a strategic advisory firm that provides regulatory, clinical, CMC and other translational guidance for life science product development. He is an entrepreneur/executive who has held senior leadership positions in public and private pharmaceutical, biotech and medical device companies for over 25 years.

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