

Minutes of Meeting with Valisure, LLC

June 3, 2024

Attendees

FDA Participants

Patrizia Cavazzoni, Center Director, Center for Drug Evaluation and Research (CDER)
Jacqueline Corrigan-Curay, Principal Deputy Center Director, CDER
Mike Kopcha, Office of Pharmaceutical Quality
Sau (Larry) Lee, Office of Pharmaceutical Quality
Jill Furman, Office of Compliance
Francis Godwin, Office of Compliance
Carol Bennett, Office of Regulatory Policy
Sharon Coleman, Office of Regulatory Policy
Courtney Cunningham, Office of Executive Programs

Valisure, LLC Participants

Chip Philips, CEO
Jill Nailor
Wolfgang Hinz
Niki Carelli

Between March 2021 and March 2024, Valisure, LLC (Valisure) submitted four citizen petitions involving the potential for benzene contamination or degradation in a variety of CDER-regulated products (FDA-2024-P-1130 (benzoyl peroxide); FDA-2021-P-1193 (antiperspirants); FDA-2021-P-0497 (sunscreens); FDA-2021-P-0338 (hand sanitizers)). Valisure subsequently requested a meeting with CDER to share information about its business evolution and future vision. On June 3, 2024, CDER met with representatives from Valisure to hear about Valisure's business and future plans and to share information about appropriate analytical testing approaches for the work that Valisure does.