

Annual Declaration Pursuant to California Health & Safety Code §§ 119400-119402

Alfasigma USA, Inc. and its subsidiary Brand Direct Health, L.L.C. (collectively referred to as the “Company”) is committed to complying with all applicable laws, regulations and industry standards. The Company has developed a Corporate Compliance Program (“CCP”) customized to fit our Company’s different business operations, the size of our Company, and the unique environment in which we operate. The CCP was developed in accordance with the U.S. Department of Health and Human Services Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers published in April 2003 (OIG Guidance) and includes policies consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care Professionals (PhRMA Code).

Our CCP is dynamic, involving not only our Company’s Code of Conduct and numerous Company policies, but also the commitment to our patients, physicians, employees, contractors, and Board of Directors to make the program effective. It is designed to prevent, detect and remediate violations of law, regulations and Company policies, as well as to promote an ethical culture that will, among other things, guide our interactions with healthcare professionals and healthcare entities. In the event that the Company becomes aware of any potential or actual violations of law, regulations or policy, an investigation will be triggered and, if necessary, followed by appropriate remedial or corrective actions in accordance with the Company’s CCP. It involves regular assessment and adjustment to ensure that the program is responsive to the Company’s evolving business needs.

The Company hereby declares that, to the best of its knowledge, and based on its good faith understanding of all applicable statutory requirements, the Company is in compliance with its CCP and requirements of California Health and Safety Code §§ 119400-119402.

Copies of this annual written declaration of compliance may be obtained from our website, <https://www.alfasigmausa.com>, or by calling the toll-free number 1-844-583-1950.

This declaration is made on September 1, 2020.