AQST Website Statement for California Comprehensive Compliance Program

COMPREHENSIVE COMPLIANCE PROGRAM DESCRIPTION PURSUANT TO CALIFORNIA HEALTH & SAFETY CODE §119400-119402

Aquestive Therapeutics Inc. (“Aquestive”) has adopted a Comprehensive Compliance Program (“CCP”) in accordance with the requirements of the California Health & Safety Code §119402. The CCP provides guidance for our employees when interacting with health care professionals and customers. The CCP was developed drawing on key elements of the PhRMA Code on Interactions with Health Care Professionals (2009), the April 2003 publication, “Compliance Program Guidance for Pharmaceutical Manufacturers” issued by the Office of Inspector General (OIG), U.S. Department of Health and Human Services, as well as AMA and ACCME guidance, and our understanding of industry leading practices.

Aquestive Therapeutics, Inc. (“Aquestive”) is committed to ethical, moral and legal business conduct. The CCP provides guidance for our interactions with health care professionals and customers; however, it does not include all laws and regulations applicable to its employees, officers, directors and vendors. An overview of Aquestive’s CCP is below.

Written Standards of Conduct :

Aquestive expects employees, officers, directors and vendors to interact with healthcare providers and customers in compliance with this CCP, Aquestive’s Code of Conduct and compliance policies, procedures, and applicable laws, regulations and industry guidelines. The CCP provides Aquestive representatives with guidance regarding interactions with health care providers and health care entities. Members of the sales and marketing department receive Aquestive’s Code of Conduct, which includes additional compliance guidance.

Compliance Officer:

Aquestive has a Corporate Compliance Officer who reports directly to senior management and the Board. The Corporate Compliance Officer’s primary responsibilities include:

- Oversight of CCP day-to-day operations;
- Developing and implementing policies, procedures and practices to administer the CCP;
- Aquestive’s compliance training activities, including dissemination of guidelines, policies and disciplinary guidelines;
- Developing and executing auditing and monitoring processes to assure adherence with the CCP;
- Monitoring Aquestive’s Compliance Hotline and responding as appropriate;
- Investigating compliance matters, including recommendations and oversight of any required disciplinary or other corrective actions;
- Enhancing effectiveness of the CCP based on observations, findings and industry developments.
Training and Education

Aquestive’s Code of Conduct and relevant job-specific materials are distributed to newly hired employees engaged in sales and commercial operations. Each new hire must agree in writing to comply with Aquestive’s CCP. All Aquestive employees receive training and follow-up training at least annually to all employees who have sales and marketing responsibilities.

Lines of Communication

Aquestive employees are encouraged to promptly communicate compliance issues and concerns. Employees receive instruction that any actual or perceived problem should be reported to their supervisors, the HR Department, the Corporate Compliance Officer or the Legal Department. Aquestive has a non-retaliation policy for any employee raising concerns or issues of legal, regulatory or policy compliance. The taking of any such retaliation by any employee, officer or director is grounds for disciplinary action. Aquestive operates an anonymous toll-free Compliance Hotline administered by a third party to facilitate the reporting of potential compliance violations and thoroughly investigated.

Auditing and Monitoring

The Corporate Compliance Officer and other personnel periodically monitor and audit Aquestive activities to ensure CCP compliance. Actions include periodic reviews of financial and other records related to interactions with healthcare professionals, and reporting and monitoring of participation of employee training.

Disciplinary Guidelines; Investigation; Corrective Action

The Corporate Compliance Officer and Aquestive’s HR Department oversee investigations of compliance-related issues. Aquestive is committed to responding promptly to non-compliance with CCP or policies and taking appropriate corrective action. Disciplinary actions, ranging from verbal reprimand, written warning, suspension and termination are determined on a case-by-case basis and are set forth in the Code of Conduct and employee handbooks.

Annual Spending Limit

California law requires pharmaceutical companies to voluntarily adopt a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company and its employees and representatives may give or otherwise provide to an individual medical or health care professional in California.

Aquestive has established a specific annual aggregate dollar limit of $1500 on gifts, promotional materials, items or activities that Aquestive may provide to an individual medical or health care professional in California. The annual limit does not include: (i) drug samples given to physicians and healthcare professionals intended for free distribution to patients, (ii) financial support for continuing medical education forums, (iii) financial support for health educational scholarships, and (iv) payments made for legitimate professional services.
DECLARATION OF COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE §119402

Aquestive hereby declares that, to the best of its knowledge, based on its good faith understanding of the requirements of California Health & Safety Code §119400-119402, Aquestive’s CCP adheres to the statutory requirements. Aquestive also declares based on its knowledge, information, and belief, that it is in material compliance with its CCP.

Aquestive will post an Annual Declaration of Compliance on its website each calendar year. Requests for copies of this CCP and the Annual Declaration of Compliance (upon posting) may be made by calling Aquestive’s Compliance Hotline toll-free at (XXX) XXX-XXXX or can be downloaded from Aquestive’s website www.aquestive.com.

Dated: [_____]