

Annual Declaration for Purposes of California Health and Safety Code, §§ 119400-119402



May 1, 2024

ANNUAL DECLARATION FOR PURPOSES OF CALIFORNIA HEALTH & SAFETY CODE, §§ 119400-119402

Section 119402 of the California Health & Safety Code mandates that pharmaceutical companies implement a Comprehensive Compliance Program that aligns with the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Compliance Guidance") and includes policies for adherence to the Pharmaceutical Research and Manufacturers of America Code ("PhRMA Code"). This law also requires the Comprehensive Compliance Program to establish an annual limit for certain items and activities provided to healthcare professionals covered by California law. Additionally, each manufacturer must make its Comprehensive Compliance Program and an annual declaration of compliance publicly available.

GC Biopharma USA, Inc. ("GCBP US" or "Company") has dedicated significant resources to the creation of its policies, procedures, and processes that constitute its Comprehensive Compliance Program, which includes an annual limit for items and activities provided to healthcare professionals in California. In developing these elements, the Company considered the OIG Compliance Guidance and PhRMA Code. It is important to note that neither the OIG Compliance Guidance nor the PhRMA Code constitutes a compliance program by itself. Instead, these documents offer voluntary guidelines to consider when developing or updating a compliance program, and they must be tailored to fit each company's unique circumstances. The Company has adapted the principles and objectives of these guidelines to meet its specific needs. Therefore, GCBP US believes that its Comprehensive Compliance Program aligns with a reasonable interpretation of the OIG Compliance Guidance and the PhRMA Code.

As of the date of this declaration, the Company asserts that it is in substantial compliance with its Comprehensive Compliance Program. The OIG acknowledges in its Compliance Guidance that the implementation of a compliance program may not eliminate improper conduct within a pharmaceutical manufacturer's operations. Consequently, this declaration is not intended to suggest that the Company has not identified individual instances where an employee or agent may have violated one or more provisions of its Comprehensive Compliance Program. In such cases, the Company takes reasonable and appropriate remedial or corrective actions consistent with its Compliance Program.

The Company's Comprehensive Compliance Program and this Annual Declaration are publicly available on our website, <https://gcbiopharma.us/>.