



UCB COMPLIANCE PROGRAM

I. INTRODUCTION

UCB is committed to establishing and maintaining an effective compliance program in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”) (May 2003). The UCB Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct.

The purpose of our Compliance Program is to provide the necessary guidance and training to our employees to prevent and/or detect violations of law or company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is UCB’s expectation that employees will comply with compliance policy and standard operating procedures. In the event that UCB becomes aware of violations of law or company policies or procedures, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

UCB has described below the fundamental elements of our Corporate Compliance Program. As HHS-OIG calls for in its Guidance, we have tailored our Compliance Program to fit the unique environment of our company. Moreover, our Compliance Program is dynamic; we regularly review and enhance our Compliance Program to meet our evolving compliance needs.

II. Overview of Compliance Program

1. Leadership and Structure.

- **Compliance Officer.** We have designated a senior-level official to serve as our Compliance Officer. The Compliance Officer serves as the focal point for compliance activities. We are committed to ensuring that this official, as Compliance Officer, has the ability to effectuate change within the organization as necessary and to exercise independent judgment. This senior-level official is charged with the responsibility for developing, operating and monitoring the Compliance Program. The Compliance Officer reports to the President of UCB and periodically makes reports to UCB leadership on the progress and status of the company’s Compliance Program.



2. **Written standards.**

- The HHS-OIG Guidance has identified several potential risk areas for pharmaceutical manufacturers, and has called on companies to develop compliance standard operating procedures in these risk areas. These risk areas are (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. UCB has adopted standard operating procedures to address these risk areas. UCB also has adopted standard operating procedures to implement the PhRMA Code on Interactions with Health Care Professionals.
- We also have established spending limits for certain promotional activities directed toward healthcare professionals in California. The annual limit we have established is \$1700.

3. **Education and Training.** A critical element of our Compliance Program is the education and training of our employees on their legal and ethical obligations under applicable laws and company policies, including federal health care program requirements. UCB is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected personnel. Moreover UCB will regularly review and update its training programs, as well as identify additional areas of training on an “as needed” basis. UCB requires compliance training for all new hires and annual training for existing employees. This training is tailored to the employees’ job functions when necessary.

4. **Internal Lines of Communication.** UCB is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know who to turn to for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted open-door policies, as well as confidentiality and non-retaliation policies. UCB also utilizes a hotline number to ensure that employees have a confidential, anonymous means of reporting compliance issues.

5. **Auditing and Monitoring.** UCB’s Compliance Program includes efforts to monitor, audit, and evaluate compliance with the company’s compliance policies and procedures. We note that in accordance with the HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing vary according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations. The areas to be audited are selected by the Compliance Officer and audits are conducted by the Compliance Officer based on the relative degree of risk identified by a risk assessment and ongoing monitoring of the risk areas.



- 6. Responding to Potential Violations.** UCB's Compliance Program includes clear disciplinary policies that set out the consequences of violating the law, company policy, or standard operating procedures. Our policies provide for sanctions that are appropriate to the severity of the violation. Although each situation is considered on a case-by-case basis, we will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations. In addition, UCB screens employees against the HHS OIG and GSA exclusion/debarment lists.

- 7. Corrective Action Procedures.** A Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective Compliance Program may not prevent all violations. As such, our compliance program requires the company to respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations. UCB has implemented a policy that governs the conduct of investigations. These investigations are led by the Compliance Officer with assistance from business management personnel when needed.