

Declaration for California Compliance Law

As part of Mentor Worldwide LLC.'s ongoing efforts in the area of compliance, we have developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of this declaration, Mentor Worldwide LLC. is in compliance with our Comprehensive Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402. Dated: July 1, 2008 Program Description

Program Description

NOTICE: this information is provided pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765), which requires certain pharmaceutical and medical device companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products

Introduction Mentor Worldwide LLC. has established a program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, Mentor Worldwide LLC. recognizes that adherence to these standards can be furthered through a compliance program that is informed by the *Compliance Program Guidance for Pharmaceutical Manufacturers*, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the "OIG Guide"). The OIG Guide advises that effective compliance programs are comprised of seven elements. As described below, these elements form the basis of Mentor Worldwide LLC.'s program for compliance with the standards regulating the marketing and promotion of its products.

Overview of Compliance Program

1. **Written Policies and Procedures** Mentor Worldwide LLC. has written policies to assure substantial compliance with the applicable laws and regulations and standards governing the marketing and promotion of our products. Among these standards are recognized industry codes of conduct including the *Code of Ethics on Interactions with Health Care Professionals*, published by the Advanced Medical Technology Association ("AdvaMed"). Mentor Worldwide LLC. has established written policies that govern activities involving communicating with customers about the appropriate use of our products including appropriate instruction, education, training, service and technical support required for the safe and effective use of our products. Mentor Worldwide LLC. also has policies governing activities involving the advancement of scientific and educational activities supporting medical research and education. These policies include:
 - a. **Policy on Educational Grants and Research Grants** Mentor Worldwide LLC. may provide grants for specific educational purposes that benefit patients and customers. These may include, but are not limited to, continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized patient education. Funding of educational programs will generally be provided only to organizations and institutions and not to individual practitioners. Research grants to support customer-initiated research may be provided for programs involving research in areas of legitimate interest to the company. All requests are subject to scientific review prior to funding approval.
 - b. **Policy on Charitable Contributions and Patient Assistance** Mentor Worldwide LLC. will consider charitable contributions and requests for patient assistance in the areas of women's health, health care education, access to health care and community responsibility, consistent with Mentor Worldwide LLC. policies.
 - c. **Policy on Travel Expense Reimbursement for CME, Promotional or Product Training Meetings** Mentor Worldwide LLC. will, with very limited exceptions that are in accordance with nationally recognized standards, not reimburse for travel and lodging expenses of attendees at promotional and educational programs. Mentor Worldwide LLC. may reimburse attendees for their reasonable travel and lodging expenses associated with attendance at product training meetings. Product training meetings will be conducted in locations conducive to the exchange of information such as educational or conference. Where face-to-face or hands-on customer training is reasonably necessary for the safe and effective use of Mentor Worldwide LLC.'s medical device products is required, Mentor Worldwide LLC. may provide training at company facilities, at independent teaching centers such as medical institutions, or in other appropriate settings.
 - d. **Policy on Business Meals** Mentor Worldwide LLC. may occasionally offer a modest meal as part of an educational presentation or a business discussion. The appropriate focus of these activities is directed to an informational presentation or discussion; therefore, venues that feature entertainment or recreation, and attendance by spouses or guests, are not permitted. Modesty is

to be judged by local standards, but in general cost of meals with customers should not exceed \$25 for breakfast, \$35 for lunch or \$125 for dinner.

- e. **Policy on the Provision of Educational and Practice-Related Items** On occasion, Mentor Worldwide LLC. representatives may provide items with direct patient benefit to customers. These items must be of reasonable value (other than medical texts and anatomical models, less than \$100; medical texts and anatomical models must be less than \$300) and infrequent.
 - f. **Total Annual Dollar Limit for Meals, Educational or Practice-related Items and Expense Reimbursement for Product Training Meetings** Mentor Worldwide LLC., has established an annual limit of \$1,500 for meals and educational or practice-related item as the aggregate value of the items or activities that may be provided to California health care professionals pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765).
 - g. **Policy Prohibiting Entertainment During Sales Functions** In general entertainment (e.g. sporting events, golf outings, concerts, hunting, etc.) is not permitted as part of Mentor Worldwide LLC's sales activities.
2. **Assigned Compliance Officer:** Mentor Worldwide LLC. has appointed a Health Care Compliance Officer. Our Health Care Compliance Officer has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management. Mentor Worldwide LLC. has established a Health Care Compliance Committee. The committee is comprised of the company's Health Care Compliance Officer and members of the company's management team. The Health Care Compliance Committee is the Health Care Compliance leadership team.
 3. **Training** Mentor Worldwide LLC. has an annual Health Care Compliance training process that includes testing and annual certification of appropriate employees. The training covers applicable guidelines governing our compliance program. Employees are also trained on the consequences of failure to comply with the requirements of the company's compliance program.
 4. **Communication** Mentor Worldwide LLC. encourages open and candid discussion between management and employees regarding any compliance concerns. Mentor Worldwide LLC. employees are encouraged to report their concerns to their manager, to the Human Resources Department, to the Law Department or to the company's Health Care Compliance Officer.
 5. **Auditing and Monitoring** Mentor Worldwide LLC. self-assesses and periodically audits its compliance with its policies and procedures.
 6. **Enforcement and Disciplinary Guidelines.** Mentor Worldwide LLC. will take disciplinary actions in response to violation of the company's compliance policies or procedures. Mentor Worldwide LLC. will conduct a fair and diligent investigation of matters that are brought to the company's attention in order to ensure the consistent application of the company's standards.
 7. **Responses To Detected Problems and Actions To Correct Issues.** Mentor Worldwide LLC. requires a prompt and diligent response to potential violations of the company's compliance program, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include improving policies, procedures, training, communication and monitoring or may require disciplinary action to prevent future violations.