

## GUERBET LLC SUMMARY OF COMPLIANCE PROGRAM

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### Introduction

Guerbet LLC is committed to complying with all laws and regulations applicable to its marketing, promotional, educational, and research activities. To this end, Guerbet LLC has implemented and maintains a comprehensive Compliance Program incorporating the elements in (1) the "Compliance Program Guidance for Pharmaceutical Manufacturers" dated April 23, 2003 and issued by the Office of Inspector General, U.S. Department of Health and Human Services on May 5, 2003 (the "OIG Guidance") and, as applicable, (2) the version of the Pharmaceutical Research and Manufacturers of America voluntary guideline entitled "Code on Interactions with Health Care Professionals," effective January, 2009 (the "PhRMA Code").

Guerbet LLC interactions with healthcare professionals should benefit patients and enhance the practice of medicine through the safe and effective use of our products. All Guerbet LLC interactions with healthcare professionals are intended to be focused on informing the healthcare professionals about products, providing scientific and educational information, and supporting medical research and education. Our Compliance Program is an indication of our commitment to the highest standards of corporate conduct in all of our business activities.

Key elements of our Compliance Program include, but are not limited to:

- Written policies and procedures addressing specific areas of compliance concern including a Code of Conduct promoting the highest ethical principles to guide Guerbet LLC employees' activities
- Designation of a Compliance Officer to oversee the Compliance Program
- Training and education as to Compliance Program requirements
- Communication mechanisms including an anonymous reporting system for any violations of Compliance Program requirements
- Auditing and monitoring to assure proper functioning of the Compliance Program and to detect any violations
- Policies and procedures for investigation and discipline of any employee found to have violated Compliance Program requirements
- Procedures for responding promptly to detected or reported problems and implementing corrective action

As recommended in the OIG Guidance, the Guerbet LLC Compliance Program has been developed and implemented to address the areas of potential problems and risk that apply to its operations. The Compliance Program is regularly reviewed, refined, and amended as necessary to ensure compliance with all currently applicable laws, regulations, and guidance.

The elements of the Compliance Program are described below in more detail.

### (1) Written Standards

Guerbet LLC's Code of Conduct is a statement of its fundamental principles and values, indicates its firm commitment to compliance and expectations of complete compliance by all of its employees, and

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provides general ethical and compliance guidance to employees on the appropriate conduct of business activities for Guerbet LLC. Specific guidance on the conduct of Guerbet LLC's business activities, including interactions with health care professionals, is set forth in a variety of written policies and procedures that are provided to all Employees. These policies and procedures have been developed under the direction and supervision of our Compliance Officer, Legal Counsel, and Management from various functional areas to reduce and eliminate the potential risks identified in the OIG Guidance and U.S. Pharma Code of Conduct.

Guerbet LLC's written Compliance policies include, among others, specific policies placing spending limits on gifts to and for certain promotional activities directed towards health care professionals; procedures for provision of product samples; policies establishing committees for the review of promotional materials, educational information, and grants; procedures to assure data integrity pertaining to government reimbursement; and policies forbidding kickbacks and other illegal remuneration.

### **(2) Designation of a Compliance Officer**

Guerbet LLC has appointed a Compliance Officer who has the authority to exercise independent judgment in meeting his/her responsibility for overseeing and monitoring Guerbet LLC's Compliance Program, including policies and procedures, training, auditing, internal reporting, and investigations. The Compliance Officer provides regular updates on Guerbet LLC's Compliance Program and compliance-related activities to the HQ Compliance Committee and Qualified Pharmacist, President or CEO, and/or the Board of Directors.

### **(3) Education and Training**

Effective communication of company policies and procedures to its personnel at all levels and regular education and training of its officers, directors, employees, contractors, and agents as to their legal and ethical compliance obligations are key components of Guerbet LLC's Compliance Program. Training on the Compliance Policies is conducted for new employees during employee orientation, and existing employees will receive compliance training on at least an annual basis. Training on specific and emerging compliance risks is provided to employees on a periodic basis including, but not limited to, the application and consequences of the False Claims Act, Anti-Kickback Statute, OIG Compliance Program Guidance, PhRMA Code on Interactions with Healthcare Professionals, as well as other applicable federal, state, and industry rules and guidelines. Guerbet LLC annually reviews and updates its training program to ensure effectiveness and identifies additional areas of training on an as needed basis.

### **(4) Lines of Communication**

As part of its commitment to ethical and legal behavior, Guerbet LLC has an open-door policy by which employees are encouraged to communicate compliance-related questions or concerns. All Guerbet LLC USA employees are free to discuss such questions or concerns with their own manager, other members of the management team, or the Compliance Officer. Guerbet LLC requires its employees to report any actual or suspected violations of law or compliance standards so that they can be appropriately investigated and addressed and has a confidential reporting system and no retaliation policy to encourage and protect employees who report compliance concerns including interactions with health care professionals.

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### **(5) Auditing and Monitoring**

Guerbet LLC's Compliance Program includes activities to monitor, audit, and evaluate compliance with the compliance policies and procedures. In accordance with the OIG Guidance, the nature, extent, and frequency of Guerbet LLC's compliance monitoring and auditing varies according to a variety of factors, including new regulatory or statutory requirements, changes in business practices, and other considerations. The results of internal compliance audits are reported to the HQ Compliance Committee, the President/CEO, and/or the Board of Directors.

### **(6) Discipline**

Adherence to the requirements of its Code of Conduct, Compliance Program, and applicable federal health care programs is a condition of employment at Guerbet LLC and Guerbet LLC will not employ individuals or entities excluded from participation in federal health care programs. Disciplinary guidelines are provided to employees at all levels upon employment with the company and are thereafter readily available via the company's intranet. It is Guerbet LLC's expectation that employees will comply with the policies and procedures established in support of our Compliance Program. However, in the event that Guerbet LLC becomes aware of violations of law or company policies and procedures, the matter will be thoroughly investigated and, where appropriate, disciplinary action will be taken. Each situation is considered on a case-by-case basis, but Guerbet LLC will take consistent and appropriate disciplinary action to address inappropriate conduct and deter future violations up to and including termination of employment.

### **(7) Corrective Actions**

As part of its Compliance Program, Guerbet LLC has procedures to ensure that timely, complete, and objective investigations are conducted regarding suspected non-compliance with the Guerbet LLC Code of Conduct, Compliance Program policies and procedures, or applicable laws and regulations. In accordance with the OIG Guidance, the exact nature and level of thoroughness of the internal investigation will vary according to the circumstances. The investigation includes an assessment to ascertain if a gap is revealed in the policies, practices, or internal controls of the Compliance Program. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate and offenses are reported to the relevant authorities in appropriate circumstances. The results of such investigations are reported to the HQ Compliance Committee, Qualified Pharmacist, the President/CEO, and/or the Board of Directors.

### **(8) Annual Spending Limit**

Guerbet LLC has established guidance regarding appropriate interactions with health care professionals. It is policy to comply with the Pharmaceutical and Research and Manufacturers of America (PhRMA) code on interactions with Health Care Professionals, which includes limits on gifts, meals and other activities with health care professionals. Guerbet has established a maximum annual aggregate dollar limit of \$2,000.00 for gifts, promotional materials or activities provided to health care professionals. This dollar amount represents a spending cap, not a goal or average, and typically the amount spent per health care professional is anticipated to be substantially less than this maximum amount. Guerbet LLC reserves the right to change this annual limit at any time due to changing internal/external factors.