## First Horizon Pharmaceutical Corporation's Comprehensive Compliance Program and Declaration of Compliance

First Horizon's Comprehensive Compliance Program is a fundamental expression of the Company's commitment to a culture of integrity and ethics. This culture of compliance is evident from the commitments of the Company's board of directors, its Compliance Officer, and each First Horizon employee.

## Compliance with Applicable Laws and Standards

All First Horizon employees shall comply with all applicable laws and regulations, including those related to the marketing, sale, and distribution of drug products such as the Prescription Drug Marketing Act (PDMA). In addition, we adhere to certain other standards, including specifically the mandatory requirements of the "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the United States Department of Health and Human Services Office of Inspector General and published in the Federal Register on May 5, 2003 (OIG Guidance). We also adhere to the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Health Care Professionals," dated July 1, 2002 and revised January 2004 (PhRMA Code).

First Horizon employees shall also comply with all applicable federal and state fraud and abuse or "anti-kickback" laws and regulations. The fraud and abuse laws prohibit, among other things, the payment or receipt of kickbacks and other forms of improper remuneration in return for purchasing or using any products or services covered under the benefits of federal or state healthcare programs. If any First Horizon employee has any questions regarding compliance with any laws or regulations, they should consult with their supervisor or the Company's Compliance Officer or General Counsel.

First Horizon shall make independent contractors and agents who are involved in sales and marketing activities aware of the Company's Comprehensive Compliance Program.

### **Policies and Procedures**

In order to assist our employees, First Horizon has implemented written policies and procedures regarding compliance, which are incorporated in the Company's Standard Operating Procedures (SOPs). These SOPs provide clear and direct guidelines on a variety of issues, including specifically the sale and marketing of pharmaceutical products, fraud and abuse laws, and interactions with healthcare providers and other entities. In addition, the Company has adopted a Code of Business Conduct and Ethics applicable to all Company employees.

#### Gifts and Entertainment

First Horizon has established specific policies and procedures related to gifts and entertainment for health care providers. Specifically, First Horizon has adopted the PhRMA Code governing gifts to health care providers. In accordance with the PhRMA Code, First Horizon will only provide gifts and items to health care professionals that primarily entail a benefit to patients or are primarily associated with a health care professional's practice, and shall not exceed \$35 in value for any individual item. Also in accordance with the PhRMA Code, First Horizon may provide occasional meals (but no entertainment or recreational events) so long as they are modest as judged by local standards (but in no case in excess of \$100 in value for any given meal) and accompany an informational presentation or a speaker presentation involving valuable scientific and educational information. In addition to the PhRMA Code requirements, First Horizon has established an aggregate annual dollar limit of \$1,500 on any gifts, incidental meals, promotional materials, and other items and activities that it will provide to individual health care professionals in any given year.

In accordance with the PhRMA Code, the OIG Guidance, and other laws, these limits do not apply to drug samples provided to health care professionals intended for free distribution to patients, financial support for continuing education forums, and financial support for health educational scholarships. Additionally, payments for legitimate professional services provided by a health care professional, including but not limited to consulting, are not subject to the any limits, provided that the compensation does not exceed the fair market value of the services rendered and otherwise conforms to the PhRMA Code and OIG Guidance.

### **Compliance Officer**

First Horizon has appointed a Compliance Officer to oversee and monitor implementation of this Comprehensive Compliance Program. The Compliance Officer shall report to the Compliance Committee on compliance matters on a regular basis and report to the President and Board of Directors as needed. The Compliance Officer shall also have responsibility for periodically reviewing and revising the Comprehensive Compliance Program, as appropriate, to respond to changes in the Company's needs, applicable laws and regulations, or to address areas in which the Comprehensive Compliance Program may need to be modified.

#### **Education and Training**

First Horizon provides regular, effective education and training for employees that interact with healthcare providers, employees that are involved in the sale and marketing of pharmaceutical products, and employees that are in a position to prevent and reduce the risk of fraud and abuse in federal and state health care programs. This training includes training regarding the PhRMA Code, anti-kickback issues, and laws and regulations governing the marketing and sale of pharmaceutical products such as the

PDMA. New employees involved in the sale and promotion of pharmaceutical products are trained on these and other matters immediately after beginning employment with First Horizon.

## **Auditing and Monitoring**

First Horizon employs the use of audits and/or other evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems. The reviews will evaluate whether the Company has adequate policies in place covering identified risk areas, whether such policies have been implemented and communicated adequately, and whether the polices have been followed. Such auditing and monitoring will take place under the direction of the Compliance Officer and/or legal counsel. First Horizon employees shall cooperate fully in any audit.

### Reporting, Investigating, and Responding to Violations

It is the obligation of every First Horizon employee who knows of a violation of this Comprehensive Compliance Program to immediately report that violation to the employee's manager or supervisor or the Company's Compliance Officer. In addition, the Company has established a "Compliance and Ethics Hotline" for employees to report suspected misconduct anonymously and confidentially. The Hotline telephone number is **1-800-792-8117**. First Horizon does not permit retaliation of any kind against employees for good faith reports of misconduct or ethical violations and for participating in any investigation.

All reported violations of this Comprehensive Compliance Program will be promptly reviewed and investigated by the Compliance Officer or an appropriate designee. First Horizon shall promptly respond to detected violations of the Company's Compliance Program, including taking corrective action and preventative measures. First Horizon shall promptly respond to any detected violations of the Company's Compliance Program, including taking corrective action and preventative measures.

#### **Discipline for Violations**

When violations of this Comprehensive Compliance Code occur, appropriate disciplinary action will be taken. The specific disciplinary action for misconduct will vary depending upon the situation, but could range from oral warnings to suspension or termination. Each situation will be evaluated on a case-by-case basis by an employee's supervisor, Human Resources, and/or the Company's Compliance Officer, taking into account all relevant factors.

#### **Additional Information**

If any First Horizon employee has questions about this Comprehensive Compliance Program, they should seek advice from their manager or supervisor or from the Company's Compliance Officer.

# **Declaration of Compliance**

First Horizon Pharmaceutical Corporation declares that it is in compliance with this Comprehensive Compliance Program and California Code Section 119400 - 119402 (2004).

Dated: July 1, 2005

# **Additional Information**

To obtain a written copy of First Horizon's Comprehensive Compliance Program and written declaration of compliance, contact us toll-free at 1-800-461-3696.