SUNOVION PHARMACEUTICALS INC.

CORPORATE POLICY

WORKING TITLE: Sample Accountability Policy		POLICY NO: 1.09	
Supersedes:	**Approval:** **Corporate Policy Review Committee (CPRC)**	**Date Issued:** **September 10, 2009 (v1)** **Amended:** **December 21, 2012 (v2)**	**Page: 1 of 5**

SECTION 1. PURPOSE:

1.1. This Policy is intended to define the parameters pursuant to which Sunovion Pharmaceuticals Inc., together with its subsidiaries and affiliates ("Sunovion" or the "Company") may distribute prescription drug samples ("Samples") (as hereinafter defined) to a Licensed Practitioner (as hereinafter defined), and to ensure compliance with applicable laws and regulations, and industry guidance related to such Samples as further defined in Section 1.3 below.

1.2. This Policy, consistent with PDMA (as defined below), applies to all Samples provided by Sunovion either through direct mail programs or via Field Sales Representatives in the United States and Puerto Rico to a Licensed Practitioner. This Policy does not apply to coupons, vouchers or other reimbursement programs.

1.3. This Policy is intended to be consistent with the Prescription Drug Marketing Act of 1987 and it amendments ("PDMA") as set forth by the Food and Drug Administration ("FDA") in 21 C.F.R. Part 203; the PhRMA Code on Interactions with Healthcare Professionals (July 1, 2002, rev. July 10, 2008); the Anti-Kickback Statute (42 U.S.C. § 1320a-76(b)); the Department of Health and Human Services ("DHHS") Office of the Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731, May 5, 2003); DHHS regulations; the federal Food, Drug, and Cosmetic Act; relevant FDA regulations and guidances; Sunovion policies and guidances, including its Standard Operating Procedures listed in Section 5.5 below; and other statutes and regulations, including state laws governing prescription drug samples, as applicable.

SECTION 2. DEFINITIONS:

2.1. "Employee" means any person employed by the Company on a full-time, part-time, and temporary or contract basis.

2.2. "Field Sales Representative" means Employees who are engaged in field sales during which the representative details and/or samples Healthcare Professionals. The definition includes those Employees who interact with Healthcare Professionals in the context of a managed care organization or other Employees who may interact with Healthcare Professionals but are not Field Sales Representatives.

2.3. "Healthcare Professional" or "HCP" refers to: (a) physicians, nurses, nurse practitioners, pharmacists, medical assistants, and other medical professionals involved in patient care, and (b) scientists, or others who, because of their professional reputations may have an influence on clinical opinions, even though they would not be prescribing pharmaceutical products.

2.4. "Licensed Practitioner" means any person licensed or authorized by State law to prescribe and/or distribute Samples including all Healthcare Professionals.

2.5. "Policy" refers to this policy.

2.6. "Prescription Drug" means any Sunovion drug that may only be dispensed by a prescription written by a Licensed Practitioner.

2.7. "Prescription Drug Marketing Act" or "PDMA" governs the handling, storage, disposal, disbursing, requesting, returning, auditing, inventory, reconciliation, reporting and record keeping of the distribution of Samples.

2.8. "Product" refers to any Prescription Drug in the Sunovion portfolio.

2.9. "Sample" or "Sample Unit" includes a unit of a Prescription Drug in a packet, card, blister pack, bottle, container or other single package comprised of one or more dosage units of a Prescription Drug sample, intended by Sunovion to be provided by a Licensed Practitioner to a patient in its original form.

2.10. "Sample Accountability Department" is the Department responsible for establishing Sample policies, procedures, business rules and training requirements; monitoring compliance with the FDA and PDMA laws, rules and regulations applicable to Samples and fulfillment programs; and supporting Field Sales Representatives with their distribution of Samples.

2.11. "Sample Accountability Committee" or "SAC" is the committee that oversees Sunovion's Sample process and is responsible for making determinations regarding the review and use of Samples. Such Committee will consist of members from Sample Accountability, Legal Affairs, Compliance, Human Resources, Field Sales Leadership, and any other Department, as applicable.

2.12. "SOPs" means Standard Operating Procedures developed in conjunction with this Policy that specifically establish uniform procedures governing the handling and usage of Samples.

SECTION 3. APPLICABILITY AND RESPONSIBILITIES:

3.1. Applicability

3.1.1. This Policy applies to all Employees of Sunovion, and any persons acting on behalf of Sunovion, including consultants, agents, or third party vendors, who shall be obligated to follow this Policy, as appropriate, in contractual arrangements or otherwise. Any Employee who violates this Policy and any manager who knowingly permits or directs a subordinate to do so, will be disciplined accordingly, up to and including termination of employment. If a person acting on behalf of Sunovion violates this Policy, or if such person's manager knowingly permits or directs such person to do so, Sunovion shall take whatever corrective action may be necessary up to and including termination of the engagement.

3.1.2. All Employees and persons acting on behalf of Sunovion under this Policy shall participate in periodic training on its requirements.

3.2. **Responsibilities**

3.2.1. The primary responsibility for implementation and oversight of this Policy is with the Sample Accountability Department.

3.2.2. The Sample Accountability Department shall be responsible, through direct operations and through the direction of other departments, for the training, oversight, organization and function of the process involving the distribution of Samples.

3.2.3. The Sample Accountability Committee shall be responsible for evaluating and making determinations regarding situations that may arise from the distribution of Samples including, but not limited to, losses or thefts pertaining to Samples, falsification of documentation, audits, and inventory reconciliation, and any disciplinary actions related thereto.

3.2.4. The Chief Compliance and Ethics Officer ("CCO") or her/his designate shall be responsible for developing, operating, monitoring and auditing compliance with this Policy and shall assist management and Employees by providing information and advice on the implementation and continued adherence to the Policy.

3.2.5. The Compliance Department is responsible for ensuring that relevant Employees are trained on this Policy. Management is also responsible for ensuring that Employees understand that they are encouraged to ask questions about the Policy, discuss compliance issues, and report possible noncompliance to management, or to a member of the Compliance, Legal Affairs, or Human Resources Departments.

SECTION 4. GENERAL:

4.1. The PDMA allows pharmaceutical companies, such as Sunovion, to provide free prescription drugs to Licensed Practitioners either by sales representatives or through a direct mail programs. This Policy ensures compliance with PDMA, state laws, SOPs, and any other relevant policies and procedures. Since Samples can have a monetary value, if not distributed appropriately, there can be implications not only under PDMA, but also under the Federal False Claims Act or Federal Anti-kickback Act. For example, Samples must never be offered to Licensed Practitioners as an inducement to prescribe and should never be used as gifts. Samples must never be given to Licensed Practitioners in order to be sold, purchased or for personal use. Samples must also never be given to Licensed Practitioners to seek reimbursement from a payer with a false claim.

4.2. Samples are provided to Licensed Practitioners for the sole purpose of free distribution to patients.

4.3. **Specific Guidelines**

4.3.1. Each Sample that is distributed to a Licensed Practitioner must be accompanied by its respective approved Package Insert.

4.3.2. No Employee may sell, purchase, or trade, or offer to sell, purchase or trade any Sample. Samples must also never be used for personal or family use.

4.3.3. Samples should never be removed from their original labeled packaging, nor should such packaging be altered in anyway.

4.3.4. Samples must never be offered to Licensed Practitioners as an inducement for a prescription, purchase or recommendation of any Product.

4.3.5. Samples must never be used as gifts to Licensed Practitioners.

4.3.6. The handling and distribution of Sample must be compliant with all relevant and applicable SOPs.

4.3.7. Any donation or charitable contribution of a Product or Sample must be compliant with 21 C.F.R. §203.39, the Sunovion Inc. Charitable and Political Contributions Policy, and any applicable Company policies and procedures.

SECTION 5. OTHER MATTERS:

5.1 Amendment

Management reserves the right to amend this policy as appropriate at any time without prior notice, pursuant to Sunovion Corporate Policy 1.0, **"Corporate Policy Review Committee"**.

5.2 Failure to Comply

EMPLOYEES WHO VIOLATE ANY SUNOVION POLICIES AND PROCEDURES WILL BE SUBJECT TO DISCIPLINARY ACTION, UP TO AND INCLUDING TERMINATION OF EMPLOYMENT.

5.3 Reporting Concerns

Reports concerning wrongful behavior, violations or suspected violations of this or any other policy, the Code of Conduct and Ethics, law or regulation may be submitted on a confidential basis or may be submitted anonymously through Sunovion's Compliance Hotline as set forth below. Reports of violations or suspected violations of alleged misconduct or wrongful behavior will be maintained as confidential as practicable under the circumstances, and as necessary to conduct a full and fair investigation.

Reporting Hotline Options:

(a) Toll free telephone: number: 866-886-1348
(b) Via the internet at: www.ethicspoint.com

5.4 Cross-References to other Corporate Policies

Code of Conduct and Ethics

Speakers Bureau Program Requirements

Educational Grants Policy

Business Courtesies Policy

Health Professional Consultant Policy