BE IT ENACTED *by the* _____ *and the* _____ *of the State of* _____.

Section 1. Short Title

This Act shall be known as "Loss and Theft of Sample Drugs Reporting Act."

Section 2. Purpose

(1) This Act helps to ensure the safety, quality, and security of prescription drug samples within the State of _____ by requiring the reporting of certain losses and any known thefts of prescription drug samples to both the responsible state authority and the responsible federal authority in the effort to prevent the introduction, sale, and distribution of substandard, ineffective, or counterfeit prescription drugs within the State of _____.

(2) This Act supplements, but does not contradict or conflict with, the governing provisions of the Prescription Drug Marketing Act of 1987, (Public Law 100-293, 102 Stat. 95) ("PDMA"), the Prescription Drug Amendment of 1992, (Public Law 102-353, 106 Stat. 941) ("PDA"), and the regulations that implement the PDMA and the PDA, (21 CFR part 203).

Section 3. Definitions

(1) The term "prescription drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of a drug.

(2) The term "responsible state authority" means _____.

(3) The term "responsible federal authority" means the U.S. Food and Drug Administration ("FDA").

(4) The term "loss threshold" is the level established by a manufacturer, distributor, wholesale distributor, or any other entity otherwise authorized to distribute prescription drug samples within the State of _____ pursuant to Section 5 whereby any loss of prescription drug samples that exceeds that level must be reported to the responsible state authority and the responsible federal authority.

(5) The term "significant loss" means any loss of a prescription drug sample that exceeds the loss threshold and which requires a company to report the loss to the responsible state authority and responsible federal authority.

(6) The reporting requirements contained in Section 4 and Section 5 of this Act shall apply to all manufacturers, distributors, wholesale distributors, and any other entity otherwise authorized to distribute prescription drug samples within the State of _____.

Section 4. Reporting Requirements for Any Known Theft

(a) A manufacturer, distributor, wholesale distributor or any other authorized distributor shall notify FDA and _____, by telephone or in writing, of any known theft of prescription drug samples within 5 business days of becoming aware of the theft.

(b) A manufacturer, distributor, wholesale distributor or any other authorized distributor shall initiate an investigation into any known theft of prescription drug samples upon discovering the theft.

(c) A manufacturer, distributor, wholesale distributor or any other authorized distributor shall provide FDA and _____ with a complete written report, including the reasons for the investigation and the results of

the investigation, no later than 30 days after the date of the initial notification in paragraph (a) of this Section. The manufacturer, distributor, wholesale distributor or any other authorized distributor shall prepare only one written report and shall submit the same report to both FDA and _____.

Section 5. Reporting Requirements for Any Known Significant Loss

(a) A manufacturer, distributor, wholesale distributor or any other authorized distributor shall notify FDA and _____, by telephone or in writing, of a significant loss of a prescription drug sample, within 5 business days of becoming aware of the significant loss.

(1) For purposes of this Act, a significant loss is a loss of a prescription drug sample that exceeds the loss threshold for that drug as established by the manufacturer, distributor, wholesale distributor or any other authorized distributor. A significant loss is not a minor accounting or inventory error.

(2) Each manufacturer, distributor, wholesale distributor or any other authorized distributor shall be responsible for establishing its own loss threshold for each prescription drug sample that it distributes. The loss threshold established by each manufacturer, distributor, wholesale distributor or any other authorized distributor may vary by product line. A company's loss threshold for one prescription drug may differ from its loss threshold for a different prescription drug.

(3) In establishing the loss threshold for each prescription drug for which it distributes prescription drug samples, a manufacturer, distributor, wholesale distributor or any other authorized distributor shall consider any combination of the following factors:

a. The dollar amount of the loss;

b. The number of sample units lost;

c. The size of the manufacturer, distributor, wholesale distributor or any other authorized distributor;

d. The number of sales representatives of the manufacturer, distributor, wholesale distributor or any other authorized distributor;

e. The size of the total inventory of the drug for the manufacturer, distributor, wholesale distributor or any other authorized distributor;

f. The value of the total inventory of the drug for the manufacturer, distributor, wholesale distributor or any other authorized distributor;

g. A company's past experiences with sample losses;

h. Whether the drug has a particularly high potential for diversion, including any local trends or other indicators of the diversion potential of the drug;

i. The level of accuracy of the company's internal audit and security system; and

j. The circumstances surrounding the loss.

(b) A manufacturer, distributor, wholesale distributor or any other authorized distributor shall initiate an investigation into any significant loss of a prescription drug sample upon discovering the significant loss.

(c) A manufacturer, distributor, wholesale distributor or any other authorized distributor shall provide FDA and _____ with a complete written report, including the reasons for the investigation and the results of the investigation, no later than 30 days after the date of the initial notification in paragraph (a) of this Section. The manufacturer, distributor, wholesale distributor or any other authorized distributor shall prepare only one written report and shall submit the same report to both FDA and _____.

Section 6. Compliance

A company that complies with the provisions of this Act shall be immune from, and not subject to, civil or criminal penalty.

Section 7. Effective Date

This Act shall take effect within 120 days of the date of enactment.