From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Friday, November 17, 2017 10:02 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Greenstone Issues Voluntary Nationwide Recall of Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, USP Due to Possible Sub Potent and Super Potent Tablets

Greenstone LLC, a wholly owned subsidiary of Pfizer Inc., is voluntarily recalling multiple lots of diphenoxylate hydrochloride and atropine sulfate tablets, USP to the consumer level. Greenstone initiated this recall because product from these lots has the potential to be super potent or sub potent.

Diphenoxylate hydrochloride and atropine sulfate tablets are indicated as adjunctive therapy in the management of diarrhea in patients 13 years of age and older. Diphenoxylate hydrochloride and atropine sulfate tablets are contraindicated in pediatric patients less than 6 years of age due to the risks of respiratory and central nervous system (CNS) depression.

The use of this product in patients with uncontrolled diarrhea due to chronic medical conditions may predispose the patient to toxicity from either the diphenoxylate or atropine components. The product label states that over dosage can be life-threatening and symptoms may include opioid and/or anticholinergic effects including respiratory depression, coma, delirium, lethargy, dryness of the skin and mucous membranes, mydriasis or miosis, flushing, hyperthermia, tachycardia, hypotonia, tachypnea, toxic encephalopathy, seizures and incoherent speech. Respiratory depression has been reported up to 30 hours after ingestion and may recur despite an initial response to narcotic antagonists. The use of the impacted super potent product when used as labeled has a low probability of being associated with adverse events of limited severity such as lethargy, skin flush, and drowsiness. Serious adverse events such as coma and respiratory depression areimprobable. If a patient was to receive a sub potent tablet, symptoms may not be controlled. To date, there have been no reports of adverse events related to this recall.

Diphenoxylate hydrochloride and atropine sulfate tablets are packaged in bottles of 100-count (NDC 59762-1061-1) and 1000-count (NDC 59762- 1061-2). The affected diphenoxylate hydrochloride and atropine sulfate lots include the following lot numbers and expiration dates. Products were distributed nationwide to wholesalers/retailers from November 2016 through June 2017 in the United States.

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-1061-1	R83962	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93347	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93348	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93349	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93350	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93351	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	R93352	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	S57831	2021 NOV 30	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	S57832	2021 NOV 30	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-1	S57834	2021 NOV 30	2.5 mg/0.025 mg	Bottle containing 100 tablets
59762-1061-2	R93356	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-1061-2	R93357	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets
59762-1061-2	R93358	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets
59762-1061-2	R97310	2021 OCT 31	2.5 mg/0.025 mg	Bottle containing 1000 tablets

Pfizer places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Patient safety is our first priority. Greenstone has notified wholesalers/retailers to arrange for return of any recalled product.

Distributors or retailers with an existing inventory of the lots, which are being recalled, should stop use and distribution and quarantine immediately. If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. For retailers that have dispensed product to consumer customers, please notify these customers regarding the recall. For additional assistance, call Stericycle at 1-855-215-4982 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

Consumers with questions regarding this recall can contact Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1-800-438-1985, option 3 (8am to 7pm ET Monday through Friday)	Medical inquiries
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.