

Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, October 07, 2015 2:37 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: URGENT: Sterile Compounded Preparations RECALL

This is to inform you that B&B Pharmacy is recalling all lots of sterile products aseptically compounded and packaged by B&B Pharmacy and that remain within expiry due to the Food and Drug Administration's (FDA) concern over a lack of sterility assurance. The sterile products were distributed to patients, providers, hospitals, or clinics between May 1, 2015 and September 29, 2015. The recall does not pertain to any non-sterile compounded medications prepared by B&B Pharmacy.

To date B&B Pharmacy has not received any reports of product contamination and/or adverse events at any given time.

If the sterility of a compounded preparation intended to be sterile is compromised, patients may be at risk. As B&B Pharmacy takes the utmost care to ensure patient safety and out of an abundance of caution; B&B Pharmacy is asking all patients and providers that received sterile compounded products from B&B Pharmacy between May 1, 2015 and September 29, 2015, and that remain within expiry, to take the following actions:

1. Discontinue use of the products;
2. Quarantine any unused product until further instructions are received on how to return the product; and
3. Contact B&B Pharmacy at 562.866.8363 ext 3 from the hours of 9:00AM-6:00PM Pacific Standard Time Monday-Friday, or e-mail at info@bbpharmacy.com to discuss the return of any unused sterile compounded products.

Customers with questions regarding this recall can contact B&B Pharmacy at 562.866.8363 ext 3 from the hours of 9:00AM-6:00PM Pacific Standard Time Monday-Friday, or e-mail at info@bbpharmacy.com. Customers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product. Providers who have dispensed any sterile product distributed by B&B Pharmacy to a patient(s) for use outside of the provider's office should contact the patient(s) to whom product was dispensed and advise the patient(s) of this recall.

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

1. Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
2. **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 conducted with the knowledge of and at the request of the FDA.

This recall has been initiated due to non-sterility concerns. Parenteral administration of non-sterile injection products that are intended to be sterile may result in a site-specific or systemic infection, which in turn may cause hospitalization, significant morbidity (permanent organ damage), or a fatal outcome.

Drug Name/Strength	QTY	Lot	BUD
Stanozolol 200mg/ml	20ml	07162015@3	10/14/2015
Nandrolone 200mg/ml	10ml	05252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	20ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	20ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	20ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
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Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
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Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Nandrolone 200mg/ml	10ml	06252015@2	10/23/2015
Testosterone cyp. 250mg/ml	10ml	07282015@7	10/26/2015
Testosterone prop. 200mg/ml	10ml	07282015@8	10/26/2015
Testosterone cyp. 250mg/ml	10ml	07292015@6	10/27/2015
Testosterone prop. 200mg/ml	10ml	07302015@4	10/28/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	05042015@4	10/31/2015
papa/phento (30mg/1mg/ml)	10ml	05062015@17	11/2/2015
Pge 20mcg/ml	10ml	05072015@7	11/3/2015
Stanozolol 200mg/ml	20ml	08112015@1	11/9/2015
Stanozolol 200mg/ml	20ml	08112015@1	11/9/2015
Pge 20mcg/ml	10ml	05182015@3	11/14/2015
Testosterone cyp. 250mg/ml	10ml	08252015@4	11/23/2015
papa/PGE1/phento20mcg/ml	10ml	06012015@6	11/28/2015
papa/PGE1/phento(30mg/50mcg/0.5mg/ml)	10ml	06012015@7	11/28/2015
papa/PGE1/phento(22.5mg/8.33mcg/0.833mg/ml)	10ml	06012015@8	11/28/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	06022015@11	11/29/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06022015@12	11/29/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06032015@5	11/30/2015
papa/PGE1/phento(30mg/10mg/1mg/ml)	10ml	06042015@4	12/1/2015
papa/PGE1/phento(30mg/10mg/1mg/ml)	10ml	06052015@15	12/2/2015

papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06082015@4	12/5/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	06082015@5	12/5/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06082015@5	12/5/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06112015@4	12/8/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	06112015@7	12/8/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	06112015@9	12/8/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06152015@10	12/12/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06162015@6	12/13/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	06162015@7	12/13/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	06232015@12	12/20/2015
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07012015@1	12/28/2015
papa/PGE1/phento(30mg/40mcg/1mg/ml)	10ml	07022015@3	12/29/2015
papa/PGE1/phento(15mg/5mcg/0.5mg/ml)	5ml	07062015@1	1/2/2016
papa/PGE1/phento(30mg/10mg/1mg/ml)	5ml	07062015@2	1/2/2016
Pge 30mcg/ml	10ml	07062015@8	1/2/2016
papa/phento (30mg/1mg/ml)	10ml	07082015@10	1/4/2016
papa/phento (15mg/0.8333mg/ml)	5ml	07082015@4	1/4/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	07092015@6	1/5/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	07092015@7	1/5/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07092015@8	1/5/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07132015@2	1/9/2016
papa/PGE1/phento(30mg/10mg/1mg/ml)	10ml	07132015@3	1/9/2016
Pge 20mcg/ml	10ml	07152015@	1/11/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07152015@10	1/11/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	07162015@4	1/12/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07162015@6	1/12/2016
Pge 30mcg/ml	10ml	07162015@7	1/12/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	07202015@1	1/16/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	07202015@2	1/16/2016
papa/phento (30mg/1mg/ml)	5ml	07212015@2	1/17/2016
papa/PGE1/phento(15mg/5mcg/0.5mg/ml)	10ml	07272015@3	1/23/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07272015@4	1/23/2016
Pge 30mcg/ml	10ml	07272015@5	1/23/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07282015@3	1/24/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07282015@4	1/24/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07282015@5	1/24/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	07292015@4	1/25/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08032015@2	1/30/2016
papa/PGE1/phento(35mg/12mcg/1.5mg/ml)	10ml	08032015@4	1/30/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	08032015@6	1/30/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08032015@7	1/30/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08142015@10	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08142015@11	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	08142015@12	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	08142015@13	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08142015@2	2/10/2016

papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08142015@4	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08142015@6	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	08142015@7	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08142015@8	2/10/2016
Pge 30mcg/ml	10ml	08142015@9	2/10/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08182015@12	2/14/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08182015@13	2/14/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	08182015@14	2/14/2016
Pge 25mcg/ml	10ml	08242015@5	2/20/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	5ml	08242015@6	2/20/2016
papa/phento (30mg/1mg/ml)	10ml	08312015@3	2/20/2016
papa/PGE1/phento (30mg/20mcg/1mg/ml)	10ml	08312015@4	2/20/2016