



Michael R. Pence  
Governor

William C. VanNess II, MD  
State Health Commissioner

DATE: September 3, 2014

TO: All Local Health Departments  
Attn: Chief Food Inspection Officer

FROM: *Laurie Kidwell*  
Laurie Kidwell, RRT Supervisor  
Food Protection Program

SUBJECT: Martin Avenue Pharmacy, Inc. - RECALL [Drug]

AFFECTED  
PRODUCT: All in-date compounded sterile preparations

SUMMARY: Unclassified Recall; The recall is being initiated in connection with a recent FDA inspection due to observations associated with certain quality control procedures that present a risk to sterility assurance.

Attached is a full list of recalled products.

Martin Avenue Pharmacy, Inc. supplied compounded sterile preparations to the offices of licensed medical professionals and individual patients by prescription until 08/20/14 in multiple states including Illinois, Ohio and Michigan.

SUGGESTED  
ACTION: For consumer inquiry only. Consumers or health care providers with questions regarding this recall may contact Martin Avenue Pharmacy, Inc. by phone at (630) 355-6400 or toll free (888) 355-6492, Monday through Friday, 9:00 a.m. to 7:00 p.m. Central Time or by e-mail at [info@martinavenue.com](mailto:info@martinavenue.com).

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### Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## Martin Avenue Pharmacy, Inc. Issues a Voluntary Multi-State Recall of All Compounded Sterile Preparations Due to a Lack of Assurance of Sterility



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To promote and provide  
essential public health services.

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**FOR IMMEDIATE RELEASE** - August 27, 2014 – Naperville, Illinois, Martin Avenue Pharmacy, Inc. is conducting a voluntary recall of all in-date compounded sterile preparations. The recall is being initiated in connection with a recent FDA inspection due to observations associated with certain quality control procedures that present a risk to sterility assurance.

If the sterility of a compounded preparation is compromised, a patient is at risk for infection. To date, Martin Avenue Pharmacy, Inc. has received no reports of suspected infection or other injury, illness or complaints associated with the use of its compounded sterile preparations. However, in an abundance of caution, and in the interest of patient safety, Martin Avenue Pharmacy, Inc. has proactively decided to voluntarily proceed with this recall process and to cease production of compounded sterile preparations until further notice. Martin Avenue Pharmacy, Inc. is committed to compounding quality and patient safety.

Martin Avenue Pharmacy, Inc. supplied compounded sterile preparations to the offices of licensed medical professionals and individual patients by prescription until 08/20/14 in multiple states including IL, WI, OH, MI, FL, AL, and TX.

Martin Avenue Pharmacy, Inc. is notifying its customers of this recall by fax, mail, phone or email with instruction on how to return recalled compounded sterile preparations to the pharmacy. Patients and healthcare providers that have product which is being recalled should stop using the products, and follow the instructions in the recall notice. To identify which sterile products and lots are being recalled, visit <http://www.martinavenue.com/voluntaryrecall/>.

Consumers or health care providers with questions regarding this recall may contact Martin Avenue Pharmacy, Inc. by phone at (630) 355-6400 or toll free (888) 355-6492, Monday through Friday, 9:00 a.m. to 7:00 p.m. Central Time or by e-mail at [info@martinavenue.com](mailto:info@martinavenue.com). Be advised, this recall does not pertain to any non-sterile compounded medications prepared by the pharmacy.

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

- **Online:** [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm). Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Martin Avenue Pharmacy's management and pharmacists deeply regret the disruption that the voluntary recall and temporary suspension of its sterile compounding service may have on pharmacy's patients, but emphasize that patient safety is always its first concern.

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

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MEDICATION NAME

LOT  
NUMBER

ACETYLCYSTEINE (PF) 10% INHAL SOLN	08072014@64
ACETYLCYSTEINE (PF) 20% INHAL SOLN	07022014@43
ACETYLCYSTEINE (PF) 20% INHAL SOLN	08052014@1
ACETYLCYSTEINE 10% OPH SOLN	07092014@21
ACETYLCYSTEINE 10% OPH SOLN	08082014@40
ALPROSTADIL ALCOHOL 500MCG/ML INJECTABLE	05022014@19
ALPROSTADIL ALCOHOL 500MCG/ML INJECTABLE	05022014@28
ALPROSTADIL ALCOHOL 500MCG/ML INJECTABLE	06122014@17
ALPROSTADIL ALCOHOL 500MCG/ML INJECTABLE	07302014@22
ATROPINE SULFATE 0.01% OPHTHALMIC	07162014@33
ATROPINE SULFATE 0.5% OPHTHALMIC	06062014@26
ATROPINE SULFATE 1MG/ML INJECTABLE	08192014@36
ATROPINE SULFATE 2MG/ML INJECTABLE	07152014@39
BACTERIOSTATIC WATER FOR INJECTION INJECTABLE	03082014@2
BACTERIOSTATIC WATER FOR INJECTION INJECTABLE	04142014@8
BACTERIOSTATIC WATER FOR INJECTION INJECTABLE	05242014@2
BACTERIOSTATIC WATER FOR INJECTION INJECTABLE	06202014@20
BACTERIOSTATIC WATER FOR INJECTION INJECTABLE	08192014@33
BENZALKONIUM CHLORIDE/WATER FOR INJ 1% (W/V)	04292014@19
BUPIVACAINE HCL 0.25% INJECTABLE	08112014@31
CALCIUM CHLORIDE (PF) 100MG/ML INJECTABLE	08072014@61
CEFAZOLIN FORTE 25MG/ML OPH SOLN	06062014@21
CEFAZOLIN FORTE 25MG/ML OPH SOLN	06062014@25
CEFAZOLIN FORTE 50MG/ML OPH SOLN	06062014@28
CEFAZOLIN FORTE 50MG/ML OPH SOLN	08012014@16
CHLORHEXIDINE GLUCONATE 0.02% OPH SOLN	06062014@27
CHORIONIC GONADOTROPIN BUFFERED DILUENT SOLUTION SOLUTION	03182014@24
CHORIONIC GONADOTROPIN BUFFERED DILUENT SOLUTION SOLUTION	04012014@31
CHORIONIC GONADOTROPIN BUFFERED DILUENT SOLUTION SOLUTION	06032014@30
CHORIONIC GONADOTROPIN BUFFERED DILUENT SOLUTION SOLUTION	07292014@28
CHORIONIC GONADOTROPIN/MANNITOL 10000U/0.1GM POWDER	03222014@5
CHORIONIC GONADOTROPIN/MANNITOL 10000U/0.1GM POWDER	04042014@9
CHORIONIC GONADOTROPIN/MANNITOL 10000U/0.1GM POWDER	05162014@15
CHORIONIC GONADOTROPIN/MANNITOL 10000U/0.1GM POWDER	07242014@18
CROMOLYN SODIUM 1% INHAL SOLN	08062014@24
CYANOCOBALAMIN 1000MCG/ML INJ SOLN	08082014@9
CYCLOSPORINE 200MG/ML OPH SUSP	07152014@14
CYCLOSPORINE SUSPENDING VEHICLE	07032014@30
CYCLOSPORINE/CORN OIL STOCK VEHICLE OIL	06262014@39
DEXAMETHASONE SODIUM PHOSPHATE 4MG/ML INJECTABLE	04032014@13
DEXAMETHASONE SODIUM PHOSPHATE 4MG/ML INJECTABLE	06042014@5
DEXAMETHASONE SODIUM PHOSPHATE 24MG/ML INJECTABLE	08122014@14
DIAZEPAM 5MG/ML INJECTABLE	08192014@50
DIHYDROERGOTAMINE MESYLATE 1MG/ML INJ SOLN	06162014@34
DIHYDROERGOTAMINE MESYLATE 1MG/ML INJ SOLN	08142014@39

FENTANYL 2000MCG/ML INJECTABLE	07292014@37
FENTANYL 6000MCG/ML INJECTABLE	08142014@45
FENTANYL/BUPIVACAINE 3000MCG/30MG/ML INJECTABLE	08202014@31
GLYCERIN 72% (W/V)/SODIUM CHLORIDE INJECTABLE	08072014@59
HISTAMINE 0.55MG/ML INJECTABLE	08142014@27
HISTAMINE 2.75MG/ML INJECTABLE	08062014@27
HISTAMINE 2.75MG/ML INJECTABLE	08152014@30
HYALURONIDASE BASE VEHICLE (PF) SOLUTION	08192014@45
HYALURONIDASE INJ SOL (PF) 150U/ML INJECTABLE	05232014@32
HYALURONIDASE INJ SOL (PF) 150U/ML INJECTABLE	08192014@48
HYDROCHLORIC ACID/WATER FOR INJECTION 10% (W/V)	04252014@26
HYDROCHLORIC ACID/WATER FOR INJECTION 10% (W/V)	07092014@17
HYDROMORP/CLON/BUPIV 12MG/600MCG/0.2MG/ML INJECTABLE	08112014@55
HYDROMORPH/BUPIVACAINE (PF) 0.5MG/0.2MG/ML INJECTABLE	08152014@34
HYDROMORPHONE HCL (PF) 1MG/ML INJECTABLE	08182014@41
HYDROMORPHONE HCL/BUPIVACAINE (PF) 10MG/7.5MG/ML INJECTABLE	08182014@45
HYDROXOCOBALAMIN 10MG/ML INJECTABLE	07232014@15
HYDROXOCOBALAMIN 5MG/ML INJECTABLE	07232014@25
HYDROXYZINE HCL 25MG/ML INJECTABLE	08192014@51
LIDOCAINE 2% INJECTABLE	08132014@29
LIDOCAINE (PF) 1% INJECTABLE	08152014@33
LIDOCAINE 1% INJECTABLE	07202014@3
METHYLCOBALAMIN (PF) 1MG/ML INJECTABLE	05082014@15
METHYLCOBALAMIN (PF) 25MG/ML INJECTABLE	04092014@14
METHYLCOBALAMIN 10MG/ML INJECTABLE	06072014@1
METHYLCOBALAMIN 1MG/ML INJECTABLE	03212014@22
METHYLCOBALAMIN 1MG/ML INJECTABLE	05222014@19
METHYLCOBALAMIN 25MG/ML INJECTABLE	03262014@24
MORPHINE SULFATE (PF) 20MG/ML INJECTABLE	07302014@31
MORPHINE SULFATE (PF) 3MG/ML INJECTABLE	07242014@28
MORPHINE/BUPIVACAINE 5MG/2MG/ML INJECTABLE	08112014@51
NALBUPHINE 10MG/ML INJ SOLN	08182014@47
NB2014 30MG/6MG/300MCG/0.3MG/ML INJECTABLE	07152014@52
NB2014 30MG/6MG/300MCG/0.3MG/ML INJECTABLE	07202014@7
OPHTHALMIC OINTMENT BASE OINTMENT	07312014@27
PARABEN WATER FOR INJECTION	03102014@23
PARABEN WATER FOR INJECTION	05282014@16
PARABEN WATER FOR INJECTION	08132014@18
PENG/PROC/STREP/CHLOR/HYOS (VET) INJ SUSP	03312014@29
PENG/PROC/STREP/CHLOR/HYOS (VET) INJ SUSP	06262014@20
PGE 1 40MCG/ML INJECTABLE	07182014@24
PGE 1 40MCG/ML INJECTABLE	08072014@24
PGE 2 100MCG/ML INJECTABLE	06232014@47
PGE 2.5 150MCG/ML INJECTABLE	07182014@28
PGE 20MCG/ML INJECTABLE	08072014@35
PGE 20MCG/ML INJECTABLE	08182014@18
PGE 3 200MCG/ML INJECTABLE	08072014@40
PGE 4 300MCG/ML INJECTABLE	08062014@40
PHENOL 10% INJECTABLE	06062014@44
PHENOL 10% INJECTABLE	07302014@14

PHENTOLAMINE MESYLATE 5 MG/35 MG/MANNITOL TRITURATION	04032014@14
PHENTOLAMINE MESYLATE 5 MG/35 MG/MANNITOL TRITURATION	07152014@36
PHENTOLAMINE MESYLATE 5 MG/35 MG/MANNITOL TRITURATION	07242014@21
PHENYLEPHRINE 1% INJECTABLE	07182014@40
PHENYLEPHRINE 1% INJECTABLE	07252014@43
PHENYLEPHRINE 10% OPH SOLN	03222014@1
PILOCARPINE (PF) 0.25% OPH SOLN	07202014@11
POLYHEXAMETHYLENE BIGUANIDE 0.02% OPH SOLN	08112014@28
POLYHEXAMETHYLENE BIGUANIDE 2% STOCK SOLN	08112014@24
PREDNISOLONE ACETATE 50MG/ML INJECTABLE	05082014@23
PREDNISOLONE ACETATE OPHTHALMIC BASE VEHICLE OPH SUSP	03212014@23
QUAD MIX 1 12MG/1MG/10MCG/0.15MG/ML INJECTABLE	06052014@24
QUAD MIX 18MG/0.2MG/18MCG/0.02MG/M INJECTABLE	07302014@29
QUAD MIX 18MG/0.2MG/18MCG/0.02MG/M INJECTABLE	08192014@31
QUAD MIX 2 12MG/1MG/25MCG/0.25MG/ML INJECTABLE	06052014@13
QUAD MIX 30MG/1MG/10MCG/0.15MG/ML INJECTABLE	08042014@36
QUAD MIX 30MG/1MG/20MCG/0.15MG/ML INJECTABLE	06052014@16
QUAD MIX 9MG/1MG/10MCG/0.1MG/ML INJECTABLE	07182014@46
QUAD MIX 9MG/1MG/10MCG/0.1MG/ML INJECTABLE	08192014@40
RESCUE SOLUTION WITH TRIAMCINOLONE INJ SOLN	08112014@41
SODIUM TETRADECYL SO4 STOCK SOLUTION 6% SOLUTION	05142014@16
SODIUM TETRADECYL SO4 STOCK SOLUTION 6% SOLUTION	07142014@47
SODIUM TETRADECYL SO4 STOCK SOLUTION 6% SOLUTION	07152014@18
SODIUM TETRADECYL SO4 STOCK SOLUTION 6% SOLUTION	08062014@16
SODIUM TETRADECYL SULFATE (PF) 1% INJECTABLE	08182014@30
SODIUM TETRADECYL SULFATE (PF) 2% INJECTABLE	08112014@50
SODIUM TETRADECYL SULFATE (PF) 3% INJECTABLE	08062014@31
SODIUM TETRADECYL SULFATE (PF) 3% INJECTABLE	08112014@47
SODIUM TETRADECYL SULFATE (PF) 5% INJECTABLE	08062014@32
SODIUM TETRADECYL SULFATE (PF) 5% INJECTABLE	08072014@62
TACROLIMUS OIL 0.03% OPH SOLN	08072014@63
TESTOSTERONE CYPIONATE (RAYMOND LAUER) 250MG/ML INJECTABLE	08012014@34
TESTOSTERONE CYPIONATE 150MG/ML INJECTABLE	08202014@4
TESTOSTERONE CYPIONATE 200MG/ML INJECTABLE	06112014@14
TESTOSTERONE CYPIONATE 200MG/ML INJECTABLE	07312014@17
TESTOSTERONE CYPIONATE 200MG/ML INJECTABLE	08202014@1
TETRACYCLINE 250MG POWDER KITS POWDER	07152014@50
TETRACYCLINE 250MG POWDER KITS POWDER	07152014@54
TETRACYCLINE 250MG POWDER KITS POWDER	07152014@55
TETRACYCLINE 250MG POWDER KITS POWDER	07152014@56
TETRACYCLINE 250MG POWDER KITS POWDER	07152014@48
TETRACYCLINE 250MG POWDER KITS POWDER	07152014@49
TETRACYCLINE 250MG POWDER KITS POWDER	08062014@53
TOBRAMYCIN (PF) 15MG/ML OPH SOLN	08012014@7
TRIAMCINOLONE ACET (PF) 40 MG/ML INJ SUSP	06192014@16
TRIAMCINOLONE ACETONIDE SUSPENDING VEHICLE (PF) VEHICLE	06172014@27
TRIMETHOPRIM/SULFADIAZINE EXCIPIENT STOCK	12/22/2014
SOLUTION INJECTABLE 06252014@23	
TRI-MIX	
12MG/1MG/9MCG/M	07152014@2
	10/13/2014

L INJECTABLE TRI-MIX 12MG/1MG/9MCG/M	08062014@55	11/4/2014
L INJECTABLE TRI-MIX 15MG/0.5MG/10MCG /ML INJECTABLE	08132014@35	11/11/2014
TRI-MIX 30MG/0.5MG/10MCG /ML INJECTABLE	08132014@36	11/11/2014
TRI-MIX 30MG/1MG/20MCG/ ML INJECTABLE	07142014@39	9/30/2014
TRI-MIX 30MG/1MG/20MCG/ ML INJECTABLE	07262014@1	10/24/2014
TRI-MIX 30MG/2MG/10MCG/ ML INJECTABLE	08182014@23	11/16/2014
TRI-MIX 30MG/2MG/20MCG/ ML INJECTABLE	06272014@52	9/25/2014
TRI-MIX 30MG/2MG/20MCG/ ML INJECTABLE	07112014@40	9/30/2014
TRI-MIX 30MG/2MG/20MCG/ ML INJECTABLE	07252014@32	10/23/2014
TRI-MIX 30MG/2MG/20MCG/ ML INJECTABLE	08192014@24	11/17/2014
TRI-MIX 30MG/3MG/5MCG/M L INJECTABLE	07302014@33	10/28/2014
TRI-MIX 8.3 LOW DOSE 22MG/0.83MG/8.3MC G/ML INJECTABLE	06252014@32	9/23/2014
TRI-MIX 8.3 LOW DOSE 22MG/0.83MG/8.3MC G/ML INJECTABLE	08072014@57	11/5/2014
TRI-MIX SEST4 30MG/1.5MG/400MC G/ML INJECTABLE	07202014@5	9/15/2014
TRI-MIX SEST4 30MG/1.5MG/400MC G/ML INJECTABLE	07152014@1	9/30/2014
TRI-MIX ST1 30MG/1.5MG/50MCG	06102014@38	9/8/2014

/ML INJECTABLE TRI-MIX ST1 30MG/1.5MG/50MCG	06122014@9	9/10/2014
/ML INJECTABLE TRI-MIX ST1 30MG/1.5MG/50MCG	07152014@59	9/30/2014
/ML INJECTABLE TRI-MIX ST1 30MG/1.5MG/50MCG	07302014@23	10/28/2014
/ML INJECTABLE TRI-MIX ST2 30MG/3MG/100MCG/	06252014@33	9/23/2014
ML INJECTABLE TRI-MIX ST5 30MG/1.5MG/300MC	08122014@40	9/30/2014
G/ML INJECTABLE TRI-MIX ST5 30MG/1.5MG/300MC	08122014@42	11/10/2014
G/ML INJECTABLE TRI-MIX ST-9A 30MG/2MG/80MCG/	06042014@20	9/15/2014
ML INJECTABLE TRI-MIX ST-9B 30MG/2MG/100MCG/	07202014@8	10/18/2014
ML INJECTABLE TRI-MIX ST-9E 30MG/4MG/150MCG/	03142014@14	9/10/2014
ML INJECTABLE TRI-MIX ST-9E 30MG/4MG/150MCG/	08062014@49	1/20/2015
ML INJECTABLE TRI-MIX T101 17.65MG/0.59MG/5.9	06262014@17	9/24/2014
MCG/ML INJECTABLE TRI-MIX T101 17.65MG/0.59MG/5.9	07182014@38	10/16/2014
MCG/ML INJECTABLE TRI-MIX T101 17.65MG/0.59MG/5.9	07302014@24	10/28/2014
MCG/ML INJECTABLE TRI-MIX T101 17.65MG/0.59MG/5.9	08192014@14	11/17/2014
MCG/ML INJECTABLE TRI-MIX T102 17.65MG/0.59MG/10	08192014@18	11/17/2014
MCG/ML		

INJECTABLE TRI-MIX T105 30MG/1MG/10MCG/ ML INJECTABLE	06102014@44	9/8/2014
TRI-MIX T105 30MG/1MG/10MCG/ ML INJECTABLE	06262014@8	9/24/2014
TRI-MIX T105 30MG/1MG/10MCG/ ML INJECTABLE	07182014@30	10/16/2014
TRI-MIX T105 30MG/1MG/10MCG/ ML INJECTABLE	07302014@16	10/28/2014
TRI-MIX T105 30MG/1MG/10MCG/ ML INJECTABLE	08062014@29	11/4/2014
TRI-MIX T105 30MG/1MG/10MCG/ ML INJECTABLE	08132014@37	11/11/2014
TRI-MIX T106 30MG/1MG/25MCG/ ML INJECTABLE	06232014@48	9/21/2014
TRI-MIX T106 30MG/1MG/25MCG/ ML INJECTABLE	06262014@9	9/24/2014
TRI-MIX T106 30MG/1MG/25MCG/ ML INJECTABLE	08192014@29	11/17/2014
TRI-MIX T108 30MG/1.5MG/25MCG /ML INJECTABLE	07142014@43	9/30/2014
TRI-MIX T25 4.413MG/0.145MG/1. 475MCG/ML INJECTABLE	08122014@23	11/10/2014
TRI-MIX T50 8.825MG/0.29MG/2.9 5MCG/ML INJECTABLE	07142014@48	9/30/2014
VANCOMYCIN 25MG/ML OPH SOLN	06102014@40	9/8/2014
VANCOMYCIN 50MG/ML OPH SOLN	06102014@39	9/8/2014
VORICONAZOLE 10MG/ML OPH SOLN	08012014@17	10/30/2014
VORICONAZOLE 10MG/ML OPH SOLN	08142014@47	11/12/2014