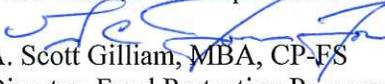




Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 30, 2013
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Lowlite Investments dba Olympia Pharmacy Recall

SUGGESTED ACTION: Unclassified Recall; Multi-state recall of all sterile drug products compounded by the pharmacy that have not reached the expiration date listed on the product. The recall is being initiated due to concerns associated with prior quality control procedures that impacted sterility assurance; Information is provided in case of consumer inquiry.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The recall includes all sterile products that Lowlite supplied to patients and offices of licensed medical professionals with a use by date of 09/25/2013 or earlier. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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.

Lowlite Investments, Inc. d/b/a Olympia Pharmacy Announces a Voluntary Multi-State Recall of All Sterile Compounded Products Compounded Between December 17, 2012, and March 27, 2013, Due to Concerns About Sterility Assurance

Contact:
Consumer
(800) 729-0276

(317) 251-9547

FOR IMMEDIATE RELEASE - May 29, 2013 – Lowlite Investments d/b/a Olympia Pharmacy ("Lowlite") today announced a voluntary multi-state recall of all sterile drug products compounded by the pharmacy that have not reached the expiration date listed on the product. The recall is being initiated due to concerns associated with prior quality control procedures that impacted sterility assurance.

In the event a sterile product is compromised patients are at risk for serious and possible life threatening infections. To date, Lowlite has received no reports of injury or illness associated with the use of our sterile products. This voluntary recall is being conducted as a precautionary measure to ensure the sterility of our sterile products, and is being conducted with the full knowledge of the FDA.

Patients should experience little to no disruption in their pharmacy services as a result of this recall.

The recall includes all sterile products that Lowlite supplied to patients and offices of licensed medical professionals with a use by date of 09/25/2013 or earlier. A list of products is attached. Lowlite will be notifying customers by phone, fax, or mail to return the products to the pharmacy.

Consumers or health care providers with questions regarding this recall may contact Lowlite by phone at 888-323-7788 or 407-673-2222 from the hours of 9:00AM- 6:00PM Eastern Daylight Time Monday through Friday, or at the following e-mail address: Brian@olympiapharmacy.com. Patients who have received any product furnished by Lowlite and have concerns should contact their healthcare provider.

Adverse reactions or quality problems experienced with the use of any Lowlite products 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.htm¹
- Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm²
Mail to address on the pre-addressed form
- Fax: 1-800-FDA-0178

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[RSS Feed for FDA Recalls Information](#)³ [[what's this?](#)⁴]

[Recall Items Product List](#)⁵

Product	LOT	Expiration Date
ACETYL-D-GLUCOSAMINE W/CHONDROITIN 200MG/ML	A5911	12/31/13
Acepromazine 25mg/ml Inj	B0112	8/31/13
ADENOSINE-MONO-PHOSPHATE INJ 200mg/ml	A5631	12/31/13
Alprostadil 2000mcg/ml	B5008	12/31/13
Alprostadil 2000mcg/ml	K5030	11/30/13
Alprostadil 2000mcg/ml	A5716	8/31/13
Alprostadil 2000mcg/ml	C5121	9/12/13
Alprostadil 2000mcg/ml	C5208	9/7/13
ALTRENOGEST 50MG/ML INJ	L5012	11/30/13
AMIKACIN SULFATE 250MG/ML INJ	B5501	8/5/13
AMIKACIN SULFATE 250MG/ML INJ	B3025	12/31/13
AMINOCAPROIC ACID 250MG/ML INJ	B3727	8/7/13
AMINOPENTMIDE 0.5MG/ML INJ	B5505	8/6/13
AMINOPHYLLINE 2.5% INJ	A5630	12/31/13
ATIPAMEZOLE 10MG/ML INJ	L3628	12/31/13
ATIPAMEZOLE 10MG/MLINJ	B5306	8/6/13
ATIPAMEZOLE 10MG/ML INJ	C3120	9/20/13
ATROPINE SULFATE 50MG/ML INJ	C5115	9/11/13
BETA ALANINE 100MG/ML / L-CARNOSINE 100MG/ML INJ	K4419	12/14/13
Betamethasone sodium Phosphate 12mg/ml Inj	A5719	6/7/13
BETAMETHASONE PHOSPHATE/ ACETATE 6 MG/ML INJ	A5810	12/31/13
Bimix	A5028	6/2/13
Blmix	B5011	6/1/13
Bimix	C4112	6/1/13
Bimix	C4208	6/20/13

BNP/DEXAMETHASONE EYE OINTMENT	B5119	10/31/13
Buprenorphine 0.3MG/ML INJ	B3727	12/27/13
Buprenorphine 0.3MG/ML INJ	C5511	9/5/13
Buprenorphine 0.3MG/ML INJ	L5312	11/30/13
CACO/COPPER 6.2MG/ML INJ	L5610	11/30/13
CALCIUM GLUCONATE 23%	A5914	12/31/13
CAL-PHOS 1000 INJ	A5211	12/31/13
CEFTIOFUR GM VIAL 50MG/ML	K5520	11/23/13
CHLORPROMAZINE HCL100MG/ML INJ	C5812	9/8/13
CHLORPROMAZINE HCL100MG/ML INJ	L4317	6/30/13
CLENBUTEROL 0.03MG/ML INJ	A0107	1/31/14
Cre-O-Pan Injection	A3021	6/2/13
Deslorelin 15mg Vial	B5328	8/3/13
Deslorelin 15mg Vial	L5011	12/11/13
Detomidine 10mg/ml Inj	C5505	9/5/13
Detomidine 10mg/ml Inj	C5107	9/7/13
DETOMIDINE W/XYLAZINE 100MG/MG INJ	A5125	12/31/13
DEXAMETHASONE SODIUM PHOSPHATE 6MG/ML INJ	L5504	8/31/13
DEXPANTHENOL 250MG/ML INJ	I5406	9/30/13
DEXTROSE 50%	A5414	12/31/13
DICLAZURIL 10MG/ML INJ	B5014	8/14/13
DIPHENHYDRAMINE 50MG/ML INJ	A3804	12/31/13
DIPHENHYDRAMINE 50MG/ML INJ	L5105	8/31/13
Disodium EDTA Inj	A5616	7/31/13
DOXAPRAM 20MG/ML INJ	B0105	8/19/13
Enrofloxacin 20mg/ml	A5011	11/30/13
ENROFLOXACIN 20MG/ML	C3811	9/8/13

ENROFLOXACIN 20MG/ML INJ	A5207	12/31/13
ESTRADIOL CYPIONATE 10MG/ML INJ	B5026	9/30/13
ESTRADIOL CYPIONATE 2MG/ML TEST CYP 50MG/ML INJ	C51212	8/12/13
Fluphenazine 25mg/ml	c5428	9/4/13
Furosemide 50mg/ml Inj	A5029	11/30/13
Gaba 50mg/Mag Sulfate 50mg/Taurine/Theanine 50mg/ml	C3729	9/7/13
GENTAMICIN 0.3%	A5308	6/30/13
GENTAMICIN 300MG/ML INJ	B5014	8/13/13
GENTAMICIN 300MG/ML INJ	C3913	9/9/13
GENTAMICIN 80MG/ML INJ	L3419	9/30/13
GENTAMICIN SULFATE 80MG/ML	B5125	8/25/13
GLUTATHIONE 200MG/ML INJ	C5110	9/11/13
GLUTATHIONE 200MG/ML INJ	A5416	12/4/13
GUANABENZ 8MG/ML INJ	C3621	9/21/13
GUANABENZ 8MG/ML INJ	L3618	10/31/13
GUANABENZ 8MG/ML INJ	A0224	6/30/13
Guanabenz 20mg/ml Inj	A0422	7/31/13
HACC 270.1 INJ	C0321	9/3/13
HACC 270.1 INJ	B5627	6/4/13
HCG 125iu/0.25ml (500iu/ml)	A3504	8/31/13
HCG 3500IU	C3105	9/5/13
HCG 10,000 IU	C3611	9/6/13
HIPPIRON 20MG/ML INJ	B5006	8/6/13
HIPPIRON 20MG/ML INJ	L5807	11/30/13
IDOXURIDINE 0.1% INJ	L5703	11/30/13
IODINE 20MG INJ	C51501	9/30/13
ITPP 50MG/ML DMG 100MG/ML INJ	A3113	7/1/13

ITTP 50MG/ML DMG 100MG/ML INJ	A3401	2/1/14
KETAMINE 100MG/ML INJ	B3411	8/11/13
KETOPROFEN Solution 10% INJ	C5122	9/22/13
L-Arginine 200MG/ML INJ	B0005	8/5/13
LIPOTONIX INJ	A3121	9/30/13
LISINAPRIL 20MG/ML INJ	A5028	6/2/13
MEDETOMIDINE 2MG/ML INJ	A5714	12/31/13
MEDROXYPROGESTERONE 150MG/ML INJ	L3727	6/1/13
MELOXICAM 5MG/ML INJ	B5426	8/26/13
MELOXICAM 5MG/ML INJ	A5110	12/1/13
METABOLASE FORTE INJ	B5021	9/30/13
METABOLASE INJ	B0101	10/31/13
METABOLASE INJ	B0013	8/13/13
Methylcobalamin 1000MCG/ML CREATINE 40MG/ML / ARGININE 100MG/ML INJ	B0001	8/1/13
METHYLCOBALAMIN 1MG/ FOLIC ACID ACID 2.5MG/ML	L3326	6/30/13
Methylcobalamin 25MG/ML INJ	L3620	12/31/13
Methylcobalamin 5000MCG/ML INJ	A3328	6/28/13
METHYLPREDNISOLONE ACETATE 80MG/ML INJ	A3104	6/4/13
METOCLOPRAMIDE 5MG/MLINJ	A5423	12/31/13
MICC	L5306	11/30/13
MICC 25/50/330 INJ	L5118	12/31/13
MICC INJ	C5214	9/21/13
MICONAZOLE 3% INJ	B5001	6/1/13
NAPROXEN 100MG/ML INJ	K5013	11/30/13
NEOMYCIN / POLYMYXIN / DEXAMETHASONE Oph DROP	A5531	6/5/13
OXYTOCIN 20UNITS/ML INJ	B5019	10/31/13
OXYTOCIN 20UNITS/ML INJ	B3525	8/25/13

OXYTOCIN 50UNITS/ML INJ	B3122	8/22/13
Papaverine 40mg/ml	B0021	8/31/13
Papaverine 40mg/ml	B0013	8/1/13
Papaverine 40mg/ml	C5122	9/22/13
Papaverine 40mg/ml	C51101	8/1/13
Papaverine 40mg/ml	C5508	9/8/13
Papaverine 40mg/ml	C5119	9/19/13
PEN-DEX-CHLOR INJ	C5108	9/10/13
Pento-Gluc 200mg/ml Inj	B0521	8/21/13
Pentosan 250mg/ml Inj	K5629	11/30/13
Pentosan 250mg/ml Inj	C51013	9/10/13
Pentosan 250mg/ml Inj	C5513	9/14/13
PHENOBARBITAL 62.5MG.ML INJ	B5128	8/28/13
PHENTOLAMINE 20MG/ML INJ	B31012	8/31/13
PHENTOLAMINE 20MG/ML INJ	B5102	8/10/13
PHENTOLAMINE 20MG/ML INJ	C5228	9/22/13
PHENTOLAMINE 20MG/ML INJ	B5012	12/31/13
PHENTOLAMINE 20MG/ML INJ	C5111	9/11/13
PHENYLBUTAZONE 200MG/ML INJ	A5224	8/1/13
PHENYLEPHRINE 1MG/ML INJ	L5017	10/31/13
PHENYLEPHRINE 1MG/ML INJ	C51301	9/30/13
PHENYLEPHRINE 1MG/ML INJ	B5312	8/31/13
PHENYLEPHRINE 1MG/ML INJ	A5209	11/1/13
POLIDICANOL 0.75% INJ	L5611	11/30/13
Policdocanol 1% Inj	B3001	6/19/13
POLIDOCANOL 1% INJ	B5014	8/14/13
Polidocanol 3% Inj	A5808	12/31/13

Policdocanol 10% Inj	C5328	9/3/13
POLIDOCANOL INC 1%INJ	A5431	6/4/13
POTASSIUM PHOSPHATE INJ	K5019	9/30/13
PRAZIQUANTEL 56.8MG/ML INJ	L3320	12/31/13
PROGESTERONE 100MG/ML IN OLIVE OIL INJ	B5007	8/7/13
PROGESTERONE EO 100MG/ML INJ	L3126	12/31/13
Quadmix	C4526	9/4/13
Quadmix	B4125	8/12/13
Quadmix	B5014	8/1/13
Sermorelin/GHRP 3mg/3mg vial	A5811	11/30/13
SODIUM IODIDIE 20% INJ	C5822	9/8/13
SODIUM SALICYLATE 40% INJ	B5020	12/31/13
SODIUM TETRADECYL SULFATE 0.125% INJ INJ	B3505	8/1/13
SODIUM TETRADECYL SULFATE 1% INJ INJ	C5001	9/30/13
SODIUM TETRADECYL SULFATE 1% INJ INJ	C5406	9/4/13
SODIUM TETRADECYL SULFATE 1% INJ INJ	C5306	9/30/13
SODIUM TETRADECYL SULFATE 2.5% INJ INJ	C5101	9/30/13
SODIUM TETRADECYL SULFATE 3% INJ INJ	B5120	10/31/13
SODIUM TETRADECYL SULFATE 3% INJ INJ	C5301	9/30/13
SODIUM TETRADECYL SULFATE 3% INJ INJ	B5428	6/4/13
SODIUM TETRADECYL SULFATE 3% INJ INJ	C5212	9/21/13
SODIUM TETRADECYL SULFATE 4% INJ	C5301	9/30/13
Stanozolol 50mg/ml Inj	B5727	8/27/13
Stanozolol 50mg/ml Inj	C5708	9/8/13
Stanozolol 100mg/ml Inj	C5706	9/6/13
TACROLIMUS 0.02% DROPS	C51012	9/12/13
TACROLIMUS 0.03%	C51201	9/12/13

TAURINE 100MG/ML INJ	C5629	10/31/13
TESTOSTERONE CYPIONATE 100MG/ML INJ	A5016	12/31/13
TESTOSTERONE CYPIONATE 200MG/ML INJ	B5028	6/5/13
Trimix	B5015	8/15/13
Trimix	C50001	8/28/13
Trimix	B5011	8/1/13
Trimix	C42215	6/22/13
Trimix	A5028	6/2/13
Trimix	B5011	6/1/13
Trimix	B5020	6/1/13
Trimix	B5004	6/5/13
Trimix	B50112	8/11/13
Trimix	C4186	6/18/13
Trimix	C4158	6/15/13
Trimix	C4149	6/14/13
Trimix	C4111	6/11/13
Trimix	B4124	8/12/13
Trimix	B4154	8/15/13
Trimix	B4198	8/19/13
Trimix	B4226	8/22/13
Trimix	B4268	8/26/13
Trimix	C40522	9/5/13
Trimix	C4118	9/1/13
Trimix	C4711	9/7/13
Trimix	C41121	9/11/13
Trimix	C4126	9/12/13
Trimix	B42715	8/27/13

TRIPLENNAMINE 20MG/ML INJ	B5620	8/20/13
TRIPLENNAMINE 20MG/ML INJ	A0322	12/31/13
VITAMIN 15 (HEMO15) INJ	A5011	7/10/13
VITAMIN A/D3/E OLIVE OIL INJ	L5303	11/30/13
VITAMIN B12 3000MCG/ML	B0020	8/20/13
VITAMIN B12 5000MCG/ML INJ	C31011	9/10/13
VITAMIN B12 CYANOCOBALAMIN 5000MCG INJ	L5203	11/30/13
VITAMIN B-BUILDUP INJ	B0122	8/22/13
Voriconazole 5% Opth Drop	A5615	6/6/13
XYLAZINE 300MG/ML INJ	A5025	6/2/13
YOHIMBINE 10MG/ML INJ	A5008	12/31/13