

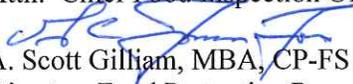


Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 29, 2013

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

FROM: 
A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Main Street Family Pharmacy, LLC Recall

SUGGESTED

ACTION: Unclassified Recall; All lots of all sterile products compounded by the pharmacy. The recall is being initiated due to seven (7) reported cases of adverse events in the form of skin abscesses, one of which appears to be fungal in nature; Information is provided in case of consumer inquiry.

From the information provided by FDA, the recalled products were distributed in the State of Indiana. These products were supplied to the offices of licensed medical professionals and patients. Sterile products included in this withdrawal were distributed nationwide. Main Street Family Pharmacy, LLC will be notifying customers by phone, fax, email, and/or mail to return the products to the pharmacy. The sterile products include all injectables with the Main Street Family Pharmacy name. 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.

Main Street Family Pharmacy, LLC Issues Voluntary Nationwide Recall of All Sterile Compounded Products

Contact

Consumer:

731-627-2221

888-658-6200

msfpcc@bellsouth.net

Media:

Joe Grillo

617-951-0000 (office)

617-429-6933 (cell)

jgrillo@nicolazzo.com

FOR IMMEDIATE RELEASE - May 28, 2013 - **Newbern, Tennessee**--Main Street Family Pharmacy, LLC today announced a voluntary nationwide recall of all lots of all sterile products compounded by the pharmacy. The compounded products that are subject to the recall are those products with a use by date on or before November 20, 2013. The recall is being initiated due to seven (7) reported cases of adverse events in the form of skin abscesses, one of which appears to be fungal in nature. An investigation into the exact source of the adverse events is still ongoing. This announcement updates a press release that was issued by the FDA on May 24, 2013.

Patients are at increased risk for serious infections in the event a sterile product is compromised. To date Main Street Family Pharmacy, LLC has only received reports of adverse events in three (3) lots of preservative-free methylprednisolone acetate (MPA). At this time, there have been no additional reports of injury or illness associated with the use of our sterile compounded products. Patient safety is our highest priority and, out of an abundance of caution, we have decided to initiate this voluntary recall to include all sterile products. The product list is attached.

These products were supplied to the offices of licensed medical professionals and patients. Sterile products included in this withdrawal were distributed nationwide. Main Street Family Pharmacy, LLC will be notifying customers by phone, fax, email, and/or mail to return the products to the pharmacy. The sterile products include all injectables with the Main Street Family Pharmacy name.

Consumers or Health Care providers with questions regarding this recall may contact Main Street Family Pharmacy, LLC by phone at 731-627-2221 or 888-658-6200 from the hours of 8:30AM-6:00PM Central Standard Time Monday-Friday or email address at msfpcc@bellsouth.net. Patients who have received any sterile compounded product supplied by Main Street Family Pharmacy, LLC and have concerns should contact their healthcare provider.

Adverse reactions or quality problems experienced with the use of sterile compounded products from Main Street Family Pharmacy, LLC may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or fax.

- **Online:** <http://www.fda.gov/MedWatch/report.htm>¹
- **Regular Mail:** use postage-paid pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>².
Mail to address on the pre-addressed form
- **Fax:** 1-800-FDA-0178

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

PRODUCT RECALL LIST

- B-12 0.5ml prefilled syringe
- Adenosine 35mg/ml 30ml
- Adenosine 3mg 2ml
- Adenosine 3mg/ml 4ml
- Adenosine 6mg/ml 2ml Vial
- Adenosine Monophosphate 50mg/ml 30ml
- Adenosine Monophosphate 35mg/ml 10ml
- Adenosine Monophosphate 50mg/ml 10ml
- AMIC-12 10ml
- AMIC-12 10ml w/out lido
- AMP injection 30ml
- B-12 (compounded) 30ml
- B-12 mixture (Methylcobalamin 5mg/Folic Acid 5mg 8ml w/ 1 ml lidocaine
- B-12 PFS
- Betamethasone 4mg 10ml sodium phosphate
- Betamethasone 6mg 10ml
- Beta NA Phosphate, Beta Acetate (PF) 6mg 10ml
- Betamethasone 6mg PF 10ml
- Betamethasone 7mg 10ml
- Betamethasone 9mg 10ml
- Betamethasone 9mg PF 1ml
- Betamethasone Acetate 9img/ml PF 10ml/MDV
- Betamethasone 10mg 10ml
- Bi-Mix 10ml
- Brompheniramine 10mg 10ml
- Depo-Testadiol 10ml
- Dexamethasone 10mg (PF) 1ml
- Dexamethasone 16mg 10ml
- Dexamethasone 16mg 30ml
- Dexamethasone Acetate 8mg/Phosphate 4mg 10ml
- Dexamethasone 8/4 30ml
- Dexamethasone 8mg 10ml
- Dexamethasone LA 16mg 10ml
- Dexamethasone LA 8mg 10mmml
- Dexamethasone 4mg 30ml
- Dexamethasone LA 16mg 30ml
- Double Strength PGE1 40mcg/ml 2ml
- Double Strength PGE1 40mcg/ml 10ml
- Estradiol Cypionate 40mg 10ml
- Estradiol Valerate 40mg 10ml
- Estradiol Cypionate 5mg 10ml
- Estradiol Pellet 20mg
- Estradiol Pellet 37.5mg
- Estradiol Pellet 50mg
- Estradiol Pellets 10mg
- Estradiol Pellets 12.5mg

- Estradiol Pellets 12mg
- Estradiol Pellets 15mg
- Estradiol Pellets 25mg
- Estradiol Pellets 31mg
- Estradiol Pellets 6mg
- Glutathione "Reduced" 200mg/ml 30ml
- Gluthione 150mg/ml 30ml
- Gomenol 10ml
- HCG + Mannitol 5000u
- HCG 100 iu prefilled syringes
- HCG 10000u
- HCG 1000iu PFS
- HCG 11,000U
- HCG 110 iu prefilled syringes
- HCG 11000u/Methylcobalamin 8mg 10ml
- HCG 11000 w/B-12 (cyanocobalamin)
- HCG 12000u
- HCG 125 iu prefilled syringes
- HCG 140 iu prefilled syringes
- HCG 15,000u
- HCG 15000u w/b-12
- HCG 1500iu PFS
- HCG 170 iu prefilled syringes
- HCG 175 iu prefilled syringes
- HCG 180 iu prefilled syringes
- HCG 20,000u
- HCG 200 iu prefilled syringes
- HCG 2000IU
- HCG 2000iu PFS
- HCG 210 iu prefilled syringes
- HCG 220 iu prefilled syringes
- HCG 225 iu prefilled syringes
- HCG 230 iu prefilled syringes
- HCG 240 iu prefilled syringes
- HCG 250 iu prefilled syringes
- HCG 2500u
- HCG 260 iu prefilled syringes
- HCG 270 iu prefilled syringes
- HCG 275 iu prefilled syringes
- HCG 280 iu prefilled syringes
- HCG 290 iu prefilled syringes
- HCG 300 iu prefilled syringes
- HCG 3000IU

- HCG 310 iu prefilled syringes
- HCG 320 iu prefilled syringes
- HCG 330 iu prefilled syringes
- HCG 340 iu prefilled syringes
- HCG 350 iu prefilled syringes
- HCG 360ium PFS

- HCG 370 iu prefilled syringe
- HCG 380 iu prefilled syringes
- HCG 390iu prefilled syringes
- HCG 40,000u
- HCG 400 iu prefilled syringes
- HCG 450 iu prefilled syringes
- HCG 5,000U
- HCG 50 iu prefilled syringes
- HCG 500 SL tablet
- HCG 500/B-12 300 tablet
- HCG 500/Test 200 troches (soy base)
- HCG 5000iu
- HCG 5000iu kit (Needle & 5ml syringe, Bacteriostatic Water 30ml, 2 Alcohol prep pads
- HCG 500u/ml w/methylcobalamin 1mg/ml 10ml
- HCG 60 iu prefilled syringes
- HCG 7000u
- HCG 8,000u
- HCG 80 iu prefilled syringes
- L-Arginine 100mg/ml 30ml
- L-Carnitine 30ml
- L-Carnitine 500mg/ml 50ml
- L-glutamine 30mg/ml 30ml vial
- L-glutathione 200mg/ml 30ml vial
- Lidocaine 2% MPF 2ml-compounded
- Lidocaine 4%/Phenylephrine 1% 1ml
- Lidocaine 4%/Phenylephrine 1% 5ml
- Lincomycin 300mg (Preservative Free) 10ml
- Lincomycin 300mg w/lidocaine 10ml
- Lipo-Shot 30ml
- Lipo B = Mic w/B5 12.5/B6 25/B12 .25/Lido 50ml
- Lipo B Complex 30ml
- Lipo B Complex 50ml
- Lipo Blast (Mic w/B1,B2,B3,B5,B6,B7,B12, AMP & Lido) 50ml
- Lipo Blast w/o adenosine (Mic w/B1,B2,B3,B5,B6,B7,B12, & Lido) 50ml
- Lipo C 30ml
- Mic w/B5/B6/B12/Lido/Amp 50ml
- Mic w/B-12 .25/AMP 12.5mg/Lidocaine 50ml
- Lipotonix B
- Lipotonix Plus-Mic B Complex Fat Burner 30ml
- Lipotonix Plus 10ml
- Lipotonix Plus 30ml
- Lipotonix Plus 30ml w/o methionine
- Lipotonix Plus w/Procaine/Chromium 10ml
- Lipotropic 1.5ml PFS
- Lipotropic 10ml
- Lipotropic 10ml with B-12 and L- Carnitine
- Lipotropic 1ml PFS
- Lipotropic 2ml PFS
- Lipotropic 30ml
- Lipotropic 30ml w/o methionine

- Lipotropic 50ml
- Lipotropic 50ml w/L-Carnitine
- Lipotropic 50ml w/o methionine
- MALE HCG PK (250, 260, 270, 280iu)
- MALE HCG PK 2nd month (290, 300, 310, 320iu)
- MALE HCG PK 3rd month (320, 330, 340, 350iu)
- Medroxyprogesterone 150mg PF 1ml
- Medroxyprogesterone 150mg w/lidocaine 10ml
- Medroxyprogesterone 150mg/ml 10ml
- Medroxyprogesterone 150mg w/lidocaine 1ml
- Medroxyprogesterone (PF) 150mg/ml 10ml
- Medroxyprogesterone 150mg w/lidocaine 5ml (compounded)
- Methylcobalamin 100mcg/ml 30ml
- Methylcobalamin 1000mcg/ml 30ml
- Methylcobalamin 1mg/ml 50ml
- Methylcobalamin 1mg/ml 30ml
- Methylcobalamin 30ml
- Methylcobalamin/Folate 5ml
- Methylcobalamin 12.5mg/ml 10ml
- Methylpred 80mg w/lido 1ml
- Methylpred 100mg 10ml
- Methylpred 100mg w/lidocaine 10ml
- Methylpred 20mg PF 5ml
- Methylpred 40mg w/lidocaine 10ml
- Methylpred 40mg PF 10ml
- Methylpred 40mg PF 1ml
- Methylpred 40mg PF 2ml
- Methylpred 40mg PF 5ml
- Methylpred 40mg w/lidocaine 1ml
- Methylpred 40mg 10ml
- Methylpred 80mg (Preservative Free) 10ml
- Methylpred 80mg 10ml

- Methylpred 80mg 1ml
- Methylpred 80mg PF 1ml
- Methylpred 80mg PF 5ml
- Methylpred 80mg w/lidocaine 10ml
- Methylpred 80mg w/lido 30ml
- Mic .05ml prefilled syringe
- Mic 25/50/50 30ml
- Mic/Cyanocobalamin 25/50/50 50ml
- MIC 25/50/50 formula w/333mg B-12 10ml
- Mic 30ml
- Mic B-Complex 30ml
- Mic B-Complex 50ml
- Mic B w/Amp Mix 50ml
- Mic Combo w/methylcobalamin (Methionine/Inositol/Choline)175mcg/25/50/50 30ml
- Mic Ultra (Methionine Free) 10ml
- Mic Ultra 30ml- Sulfur Free
- Mic Ultra 10ml

- Mic Ultra 30ml
- Mic Ultra 50ml
- Mic Ultra 50ml- Sulfur Free
- Mic Ultra 50ml- Sulfur Free w/ Lido
- Mic w/B-12 30ml
- Mic w/B-12 50ml
- Mic w/B6/B12/Lido 50ml
- Mitomycin 0.02%
- Mitomycin 0.04% 2.5ml
- Mitomycin C 1/2 Strength
- Mitomycin 20mg
- Mitomycin 2ml (full Strength)
- Mitomycin 40mg Compounded
- Mitomycin C
- Post-menopausal HCG Pk (250iu, 270iu, 290iu, 310iu)
- Post-menopausal HCG Pk 2nd month (310iu, 320iu, 320iu, 330iu)
- Post-menopausal HCG Pk 3rd month (340iu, 340iu, 350iu, 350iu)
- Pre-menopausal HCG PK (200iu, 220iu, 240iu, 260iu)
- Pre-menopausal HCG PK 2nd month (270iu, 280iu, 290iu, 300iu)
- Pre-Menopausal 3rd month (310iu, 320iu, 330iu, 340iu)
- Single Strength PGE1 20mcg 2ml
- Single Strength PGE1 20mcg/ml 10ml
- Taper A prefilled syringes
- Taper Pack B
- Taper Pack C
- Testosterone 200mg 10ml (compounded)
- Testosterone 200mg 30ml (compounded)
- Testosterone 210mg 10ml (compounded)
- Testosterone Cypionate 300mg/ml 10ml
- Testosterone Cypionate 250mg 10ml
- Testosterone Cypionate 210mg 10ml
- Testosterone Cypionate 300mg/ml 10ml
- Testosterone Pellet 112.5mg
- Testosterone Pellet 112mg
- Testosterone Pellet 12.5mg
- Testosterone Pellet 87.5mg
- Testosterone Pellets 100mg
- Testosterone Pellets 125mg
- Testosterone Pellets 200mg
- Testosterone Pellets 220mg
- Testosterone Pellets 225mg
- Testosterone Pellets 25mg
- Testosterone Pellets 37.5mg
- Testosterone Pellets 50mg
- Testosterone Pellets 75mg
- Testosterone Propionate 100mg/ml 10ml
- Tetracaine 2%/Pontocaine 60ml
- Tri-Mix 10ml
- Tri-Mix 5ml
- Triamcinolone Acetonide 10mg PF 5ml

- Triamcinolone Diacetate 40mg 2ml Preservative Free
- Triamcinolone 40mg/ml 5ml
- Triamcinolone Diacetate 40mg/ml 5 ml
- Triamcinolone Acetonide 40mg 2ml Preservative Free
- Triamcinolone Acetonide 10mg 5ml (compounded)
- Triamcinolone 40mg 10ml (PF)
- Triamcinolone Diacetate 40mg 10ml
- Triamcinolone 40mg 1ml
- Triamcinolone Acetonide 40mg PF 10ml
- Triamcinolone 40mg/ml 10ml
- Triamcinolone Acetonide 40mg/ml 10ml
- Triamcinolone D 40mg 1ml
- Triamcinolone PF 2ml
- Trypan Blue 1ml
- Wydase 1ml
- Wydase 5ml
- Wydase 150u/ml PF 5ml

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