Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Bella Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of All Sterile Drug Products Due to Lack of Sterility Assurance

For Immediate Release

August 18, 2017

Contact

Consumers

877-235-5279

Media

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Announcement

View Product Photos

Bella Pharmaceuticals is voluntarily recalling all lots of unexpired sterile drug products due to lack of sterility assurance. The recalled products were distributed to health care facilities nationwide.

Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening. To date, Bella Pharmaceuticals has not received any reports of adverse events.

The affected products include all lots distributed April 17, 2017, to August 10, 2017, remaining within expiry, and they would be packaged in a syringe, vial or eye dropper.

The following products are being affected by this recall:

Lot	Expiration Date	Product Name	Container type	Units Distributed
070617GL	1/6/18	Glutathione 200mg/ml	30ml Vial	82units
070717MC	1/7/18	Methylcobalamin 1mg/ml	30ml Vial	30units
070717ML	1/718	Mannitol 20%	10ml Vial	10units
071217GAC	1/12/18	GAC	30ml vial	3 units
071217CC	10/12/18	Calcium chloride 10%	10ml vial	5 units

Lot	Expiration Date	Product Name	Container type	Units Distributed
BPBC3080517	2/5/18	B-Complex	30ml vial	45 units
BPMC30072917	1/29/18	Methylcobalamin 10mg/ml	30ml vial	7 units
BPMC08517	2/5/18	Magnesium Chloride 200mg	30ml vial	5 units
BPLG08517	2/5/18	L-Glutamine 100mg	30ml vial	5 units
BPMIC30072917	1/29/18	MIC 25/50/50	30ml Vial	5 units
BPLG3508717	11/7/17	Lidocaine Gel 3.5%	15ml dropper	6 units
BPPTC08717	11/17/17	Phenylephrine2.5%/Tropicamide 1%	15ml dropper	6 units
BPSB8408717	11/7/17	Sodium Bicarbonate 8.4%	10ml vial	20 units
BPFS41717	4/1/18	Fluorescein Sodium	5ml vial	644 units
3141201	9/13/17	Avastin (Bevacizumab)	BD 30g ½ and 31g 5/16 syringe	30 units
3146966	9/20/17	Avastin (Bevacizumab)	BD 30g ½ and 31g 5/16 syringe	310 units
3160608	10/5/17	Avastin (Bevacizumab)	BD 30g ½ and 31g 5/16 syringe	784 units
3146966	11/1/17	Avastin (Bevacizumab)	BD 30g ½ and 31g 5/16 syringe	646 units

“Bella Pharmaceuticals has a longstanding commitment to quality and safety. We are voluntarily issuing a recall out of an abundance of caution after several issues were identified during a recent FDA inspection of our facility,” Michael Younan, Chairman and CEO of Bella Pharmaceuticals. “We regret any impact this recall has on our loyal customers and their patients.”

Bella Pharmaceuticals is notifying its customers by email and phone, and is arranging for the return of all recalled products. Anyone with product subject to the recall should stop using it and contact the company. To return medication or request assistance related to this recall, contact Bella Pharmaceuticals at 877-235-5279, Monday through Friday, between 9 a.m. and 5 p.m. CST.

Consumers with questions regarding this recall can contact Bella Pharmaceuticals by 877-235-5279 or **e-mail address on Monday through Friday, from 9 a.m. and 5 p.m. CST**. Consumers should contact their physician or 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 (http://www.fda.gov/medwatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://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 the U.S. Food and Drug Administration.

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