



FAX COVER

From: National Distribution & Contracting, Inc. Djana Milliken – Compliance ***URGENT*** ***This is being faxed/emailed to the "bill to" account for your company. Please distribute to any/all branches.***	
To: Purchasing or Regulations Department	Date: 8/16/2016
Pages: <u>10</u> (Including cover page)	
Regarding: Major Pharmaceuticals Urgent Drug Recall	
Comments: Dear Distributor, Attached is a letter we received from Major Pharmaceuticals regarding the recall on all liquid products from October 20, 2015 through July 15, 2016. Our records indicate that you purchased one of these products from us. Please read attached letter and check your inventory for any affected product. If you have any of these products in stock please fill out NDC's attached "Request for return" form, so that we can issue you a RGA for return. <u>Also, please make note that no credit will be issued without an RGA. If you have any questions please feel free to contact me. It is very important that we receive a response, a record of receipt is very important in documentation of these types of notices.</u> Additionally, if you have distributed these products to your customers, please advise them of the recall, and have return any affected product to you. Thanks,  Djana Milliken	



PharmaTech-LLC

4131 SW 47th Ave Suite 1403

Davie FL 33314

August 8, 2016

URGENT DRUG RECALL

Dear Customer,

PharmaTech, LLC of Davie, FL, is voluntarily recalling all liquid products from October 20, 2015 through July 15, 2016 as a precautionary measure due to a potential risk of product contamination with *Burkholderia cepacia*.

If a product contains *B. cepacia*, its use could result in infections in patients with compromised immune systems and in patients with chronic lung conditions such as cystic fibrosis. Some of these infections may be serious or even life-threatening in the at risk patient population.

As part of its commitment to patient safety, PharmaTech, LLC is working to notify customers who may be in possession of the affected products.

PharmaTech, LLC is notifying its distributors and customers by recall letter and is arranging for return of all recalled products. Consumers, pharmacies, and healthcare facilities that have product which is being recalled should stop using and dispensing them immediately.

PharmaTech-LLC has not received any complaints to date of contamination in the products and the associated lot numbers listed below:

DRUG PRODUCTS:

Rugby

Diocto Syrup, Docusate Sodium 60mg/15 mL, NDC 0536-1001-85, Lot#22941505, Exp. Date 10/2017
Diocto Syrup, Docusate Sodium 60mg/15 mL, NDC 0536-1001-85, Lot#22941601, Exp. Date 01/2018
Diocto Syrup, Docusate Sodium 60mg/15 mL, NDC 0536-1001-85, Lot#22941602, Exp. Date 03/2018
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391515, Exp. Date 08/2017
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391516, Exp. Date 08/2017
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391517, Exp. Date 09/2017
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391518, Exp. Date 10/2017
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391520, Exp. Date 11/2017
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391521, Exp. Date 12/2017
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391601, Exp. Date 01/2018
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391603, Exp. Date 03/2018
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391604, Exp. Date 03/2018
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391606, Exp. Date 04/2018
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391607, Exp. Date 04/2018
Senexon Liquid, 237mL, NDC 0536-1000-59, Lot#20391609, Exp. Date 06/2018

4131 SW 47TH AVE #1403 DAVIE FL 33314 PH: 954-581-7881



Major

Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391517, Exp. Date 09/2017
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391518, Exp. Date 10/2017
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391519, Exp. Date 11/2017
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391601, Exp. Date 01/2018
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391602, Exp. Date 02/2018
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391604, Exp. Date 03/2018
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391605, Exp. Date 03/2018
Senna Syrup, 237mL, NDC 0904-6289-09, Lot#20391608, Exp. Date 06/2018

DIETARY SUPPLEMENT PRODUCTS:

Rugby

Calcionate Syrup, Calcium Glubionate Syrup 473mL, UPC 005362770851, Lot#20341601, Exp. Date 06/2018
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471516, Exp. Date 11/2017
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471517, Exp. Date 11/2017
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471518, Exp. Date 11/2017
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471519, Exp. Date 11/2017
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471520, Exp. Date 11/2017
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471521, Exp. Date 12/2017
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471601, Exp. Date 01/2018
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471608, Exp. Date 04/2018
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471610, Exp. Date 05/2018
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471613, Exp. Date 05/2018
Cerovite Liquid, 236mL, UPC 005362790590, Lot#20471614, Exp. Date 06/2018
D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691509, Exp. Date 11/2017
D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691601, Exp. Date 01/2018
D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691602, Exp. Date 02/2018
D3 Vitamin Liquid, 50mL, UPC 005368400806, Lot#20691604, Exp. Date 05/2018
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461511, Exp. Date 10/2017
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461512, Exp. Date 10/2017
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461513, Exp. Date 11/2017
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461514, Exp. Date 11/2017
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461515, Exp. Date 12/2017
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461516, Exp. Date 12/2017
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461601, Exp. Date 02/2018
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461602, Exp. Date 02/2018
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461603, Exp. Date 04/2018
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461604, Exp. Date 04/2018
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461605, Exp. Date 05/2018
Ferrous Sulfate Liquid, 473mL, UPC 005360650858, Lot#22461606, Exp. Date 05/2018
Fer-iron Liquid, 50mL, UPC 005360710804, Lot#20901507, Exp. Date 07/2017
Fer-iron Liquid, 50mL, UPC 005360710804, Lot#20901508, Exp. Date 11/2017
Fer-iron Liquid, 50mL, UPC 005360710804, Lot#20901603, Exp. Date 05/2018
Polyvitamin liquid with Iron, 50mL, UPC 00536853080, Lot#21021510, Exp. Date 07/2017
Polyvitamin liquid with Iron, 50mL, UPC 00536853080, Lot#21021601, Exp. Date 01/2018
Polyvitamin liquid with Iron, 50mL, UPC 00536853080, Lot#21021602, Exp. Date 02/2018



Polyvitamin liquid with Iron, 50mL, UPC 00536853080, Lot#21021604, Exp. Date 05/2018
Polyvitamin liquid, 50mL, UPC 005368450801, Lot#20701511, Exp. Date 09/2018
Polyvitamin liquid, 50mL, UPC 005368450801, Lot#20701514, Exp. Date 12/2017
Polyvitamin liquid, 50mL, UPC 005368450801, Lot#20701605, Exp. Date 05/2018
Polyvitamin liquid, 50mL, UPC 005368450801, Lot#20701606, Exp. Date 06/2018
Tri-Vitamin liquid, 50mL, UPC 005368501800, Lot#20731506, Exp. Date 08/2017
Tri-Vitamin liquid, 50mL, UPC 005368501800, Lot#20731603, Exp. Date 02/2018
Tri-Vitamin liquid, 50mL, UPC 005368501800, Lot#20731604, Exp. Date 06/2018
Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331510, Exp. Date 12/2017
Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331511, Exp. Date 12/2017
Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331601, Exp. Date 03/2018
Liquid Vitamin C, 118 mL, UPC 005360160975, Lot#20331602, Exp. Date 03/2018

Major

CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471602, Exp. Date 01/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471603, Exp. Date 02/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471604, Exp. Date 02/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471605, Exp. Date 03/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471606, Exp. Date 03/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471607, Exp. Date 04/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471609, Exp. Date 05/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471611, Exp. Date 05/2018
CertaVite with Antioxidants, 236mL, NDC 0904-5023-09, Lot#20471612, Exp. Date 05/2018
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701509, Exp. Date 09/2017
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701511, Exp. Date 09/2017
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701513, Exp. Date 12/2017
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701601, Exp. Date 02/2018
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701602, Exp. Date 04/2018
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701603, Exp. Date 04/2018
Poly-Vita Drops, 50mL, NDC 0904-5099-50, Lot#20701606, Exp. Date 06/2018
Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021510, Exp. Date 07/2017
Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021601, Exp. Date 01/2018
Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021602, Exp. Date 02/2018
Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021603, Exp. Date 04/2018
Poly-Vita Drops with Iron, NDC 0904-5100-50, Lot#21021604, Exp. Date 05/2018
D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691509, Exp. Date 11/2017
D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691510, Exp. Date 12/2017
D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691603, Exp. Date 03/2018
D-Vita Drops, 50mL, NDC 0904-6273-50, Lot#20691605, Exp. Date 04/2018
Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901509, Exp. Date 11/2017
Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901510, Exp. Date 11/2017
Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901601, Exp. Date 02/2018
Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901602, Exp. Date 03/2018
Ferrous Drops, 50mL, NDC 0904-6060-50, Lot#20901603, Exp. Date 05/2018
Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731506, Exp. Date 08/2017
Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731507, Exp. Date 11/2017



Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731604, Exp. Date 06/2018
Tri-Vita Drops, 50mL, NDC 0904-6274-50, Lot#20731605, Exp. Date 06/2018

DEPTH OF THE RECALL:

This recall is being carried out to the RETAIL LEVEL and is only for the specific product / lots listed above. No other lots, packages, or formulations are being recalled.

Your assistance is appreciated and necessary to prevent patient harm. For questions regarding returns, please contact PharmaTech-LLC Angelina Reyburn, Recall Coordinator.

To ensure proper credit please return recalled products to PharmaTech-LLC no later than October 8, 2016.

Any product returned in addition or in lieu of recalled product will be destroyed, without issuance of a credit.

INSTRUCTIONS TO CUSTOMERS:

1. Stop distributing and quarantine these affected products immediately.
2. Please carry out a physical count and record the needed information on the Business Reply Form which is included with this letter.
3. Fax the Business Reply Form to (954)-583-8778 attention Angelina Reyburn, Recall Coordinator within ten business days, even if you do not have the recalled product in stock.
4. Once a RMA is obtained from PharmaTech, LLC please return the recalled product to the address below using the shipping method specified in the form:

PharmaTech-LLC
4131 SW 47th Ave, Suite 1403
Davie FL 33314

5. If you have further distributed the affected products please notify your Retail/Wholesale customer immediately and have them return the product back to you. Follow the instructions in this letter to obtain any additional RMA's needed for distributed products.

See enclosed product photographs for ease in identifying the product.



Please respond by
August 30, 2016

8/16/2016

Major Pharmaceuticals

REQUEST FOR RETURN FORM

Customer Information

Account No. _____

Account Name _____

Address _____

City/State/Zip _____

Contact Name _____

Phone No. _____

Fax No. _____

Email _____

Inventory Information

Item number	Lot number	Expiration date	Quantity to return

I have read and understood the information within the accompanying notification. All relevant customers/ personnel have been informed of its contents, any necessary actions taken and records retained as part of our documentation.

We have inspected our inventory and have no product related to this recall

Completed by: _____ (Print Name /Signature/Date)

Returned Completed form to:

Fax #:

Email:

Djana Milliken

615.229-6801

compliance@ndc-inc.com

*Delivering Efficiency to Healthcare**

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