MEDICAL SUPPLY BULLETIN

HHS SUPPLY SERVICE CENTER
PERRY POINT, MD 21902
We Service the World

Jamie Cooke, Director David Wernek, QA Specialist Editor

BULLETIN 2 May 20, 2014

Manufacturer Drug Recall

ParaGard T 380A – Intrauterine Copper Contraceptive				
Lot	**NDC**	**Product Description**	**Exp. Date**	**U/I**
508004	51285-0204-01	Intrauterine Copper Contraceptive	05/2015	Single Unit
508004	51285-0204-02	Intrauterine Copper Contraceptive	05/2015	Carton of 5

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of ParaGard T 380A- Intrauterine Copper Contraceptive (6515-01-283-5192) distributed under the **Duramed Pharmaceuticals label**. This recall is being carried out due to a lack of sterility assurance.

The most likely cause for this potential sterility issue is laboratory contamination during the most recent testing in January 2014 due to a breach of environmental controls during the testing of the product. All previous annual tests, including sterility, met specifications. The organism recovered during the sterility test, *Propionibacterium* species, are considered commensal bacteria on the skin and usually nonpathogenic. Theoretical exposure to this product containing such bacteria may cause medically reversible diverse events, but the probability of serious adverse health consequences is remote. In addition the risk of introduction of an infection from product removal/insertion outweighs the risk of a sterility issue with this lot of product. Therefore, retrieval of the unit on a patient level is not warranted, and used product should not be returned.

We ask for your cooperation in taking the following action:

- Please examine your inventory, and if you have the recalled product in question immediately cease distribution / use.
- If you have purchased the product from SSC, fill out the enclosed **Return Response Form** and send with recall product.
- Mark the returned product purchased from SSC **"Recall Materials Enclosed,"** and return to:

ATTN: Leslie Ridgeway
HHS Supply Service Center,
Building 14,
Perry Point, MD 21902

- Used product are not accepted for credit.

Return the affected product before **July 30th 2014** to expedite processing of your return goods credit. Accounts will be credited upon receipt of the recalled product. Please note customers must reorder the ParaGard T 380A- Intrauterine Copper Contraceptive. If you have any questions about this recall, please contact David Wernek, Quality Assurance Specialist at 1-800-642-2244 Ext: 1110. We apologize for any inconvenience and appreciate your prompt attention to this recall.

Jamie P. Cooke

Jamie Cooke

Recall Response Form

HHS Supply Service Center

The following product has been identified as previously being stocked by HHS Supply Service Center with the manufacturer of these products being Duramed Pharmaceuticals. . If you have purchased any of these items from the HHS Supply Service Center, please complete and enclose a copy of this form with your returned goods.

ParaGard T 380A – Intrauterine Copper Contraceptive (6515-01-283-5192)				
Lot	**NDC**	**Product Description**	**Exp. Date**	**Quantity**
508004	51285-0204-01	Intrauterine Copper Contraceptive, Single Unit	05/2015	
508004	51285-0204-02	Intrauterine Copper Contraceptive, Carton of 5	05/2015	

Point of Contact (POC):_____.

Customer Number:_____.

Telephone Number:_____.

Organization:_____.

Order Number:_____.

Date: _____.

Mark the returned product purchased from SSC: **"Recall Materials Enclosed"**, and return to:

ATTN: Leslie Ridgeway
HHS Supply Service Center,
Building 14,
Perry Point, MD 21902