



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

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Steven Pearson, Director

Annette Quiñones, R.Ph. Editor

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BULLETIN NO. 7

October 10, 2012

## VOLUNTARY RECALL OF TYPHOID VACCINE

Dear Valued Customer:

As a precautionary measure, Sanofi Pasteur is voluntarily recalling 6 lots of Typhim Vi<sup>®</sup>, Typhoid Vi Polysaccharide Vaccine with potentially low antigen content. This action was taken, in consultation with the US Food and Drug Administration, because of potential lower potency of the vaccine against typhoid fever due to a lower antigen content (ie, an antigen content below the official Pharmacopeia specification limit) in some lots of vaccine.

Please note:

- There is no safety concern for the persons who received a Typhim Vi vaccine from a recalled lot.
- Persons who received a Typhim Vi vaccination from a recalled lot may have received less than the intended amount of antigen. Although Sanofi Pasteur does not have clinical trial data on the immunogenicity and efficacy of Typhim Vi vaccine with antigen content below specification, Sanofi Pasteur does not recommend revaccination earlier than otherwise indicated based on existing dose-ranging data and knowledge of the kinetics of Typhim Vi vaccine.
- Typhim Vi vaccine from lots not being recalled can be administered.

There are 5 lots of Typhim Vi vaccine prefilled syringes (NDC 49281-790-51) and 1 lot of 20-dose vials (NDC 49281-790-20) that are affected.

Lot Number	Expiration Date	NDC	UOM
E1287-1	20NOV12	49281-790-51	Prefilled Syringes
E1288-1	17NOV12	49281-790-51	Prefilled Syringes
G0481-1	07SEP13	49281-790-51	Prefilled Syringes
G0507-1	20SEP13	49281-790-51	Prefilled Syringes
G0508-1	27SEP13	49281-790-51	Prefilled Syringes
G1130-1	18MAR13	49281-790-20	20-Dose Vial

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: Quality Assurance  
HHS Supply Service Center,  
Building 14,  
Perry Point, MD 21902**

- Open containers are not accepted for credit.

Return the affected product before **November 30<sup>th</sup> 2012** to expedite processing of your return goods credit. Accounts will be credited upon receipt of the recalled product. Please note customers must reorder the Typhoid Vaccine.

If you have any questions about this recall, please contact John Diesel, Quality Assurance Specialist at 1-800-642-2244 Ext: 1128. We apologize for any inconvenience and appreciate your prompt attention to this recall.

  
Steven Pearson

# 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 Sanofi Pasteur. Please complete and enclose a copy of this form with your returned goods if you have purchased any of these items from the HHS Supply Service Center.

Typhoid Vaccine prefilled syringes 6505-00-000-7006		
Lot Number	Expiration Date	Qty
E1287-1	20NOV12	
E1288-1	17NOV12	
G0481-1	07SEP13	
G0507-1	20SEP13	
G0508-1	27SEP13	
Typhoid Vaccine 20 Dose Vial 6505-01-385-6328		
G1130-1	18-MAR13	

Point of Contact (POC): \_\_\_\_\_

Customer Number: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Organization: \_\_\_\_\_

Date: \_\_\_\_\_

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

**ATTN: Quality Assurance  
HHS Supply Service Center,  
Building 14,  
Perry Point, MD 21902**