

**Wyeth**  
P. O. Box 8299  
Philadelphia, PA 19101-8299

**Wyeth**

March 22, 2010

**URGENT - DRUG RECALL – Unapproved Rubber Formulation in Some Syringe Tip Caps**

PRODUCT:            Pevnar® Pneumococcal 7-valent Conjugate Vaccine  
                          (Diphtheria CRM<sub>197</sub> Protein)  
SIZE:                 0.5 mL single dose pre-filled syringe (10 per package)  
NDC:                 0005-1970-50 (10's)/0005-1970-49 (Singles)  
LOT NOS.:            E25197 (EXP 10/13), E28211 (EXP 10/13), E37556 (EXP 10/13), E38749 (EXP 11/13)  
DISTRIBUTION:       January 9, 2010 – March 3, 2010

TO:    Wyeth Pharmaceuticals Customers

Wyeth, now a part of Pfizer Inc, is voluntarily recalling the above four lots of Pevnar®, Pneumococcal 7-valent Conjugate Vaccine, single dose pre-filled syringes. During a routine physical inspection of Pevnar® pre-filled syringes, Wyeth determined that a potential exists for syringes to have been distributed with a rubber formulation in the syringe tip caps that was not approved for use with Pevnar®. **Wyeth performed a medical assessment and has concluded that the affected syringes present no health or safety risk to patients. Further, there would be no expected loss of potency and there is no need to revaccinate children who may have received a dose of Pevnar® from an affected syringe.**

**You should extend this recall to all dispensing level accounts.**

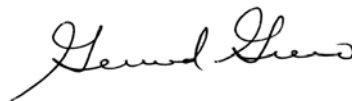
Our records indicate that products from one or more of the above lots have been shipped to you. Please examine your Wyeth inventory of Pevnar®, Pneumococcal 7-valent Conjugate Vaccine, single dose pre-filled syringes and follow the appropriate course of action described below.

1. If you have any product from the above lots, please remove it immediately from use. Contact Stericycle Inc. at 1-800-668-4391 and request a Return Kit from the Customer Service agent. Stericycle Inc. will subsequently send you a Return Kit with preprinted return address label(s), packing slip and instructions for returning the recalled product. You will receive credit for the returned merchandise.

2. If you have distributed any of these lots to subordinate accounts, please notify them of this recall to the **dispensing level** and request return of the products to you for your return to us. Please contact Stericycle Inc. at 1-800-668-4391 and request Return Kit from the Customer Service agent. Stericycle Inc. will subsequently send you a Return Kit for returning the recalled product you receive from your subaccounts. You will receive credit for the returned merchandise.
  
3. Please mark the appropriate box or boxes on the enclosed pre-paid postcard, record the quantity you will return, and send the postcard to us immediately. **Your immediate response, even if you do not have any recalled product from the subject lots, is very important to both us and the FDA in monitoring the effectiveness of this recall.**

The Food and Drug Administration has full knowledge of this recall. Wyeth apologizes for any inconvenience resulting from this recall. If you have any questions, please call our Product Quality Department at 1-800-999-9384. Thank you for your cooperation.

Sincerely,



Gerard M. Greco, Ph.D.  
Vice President  
Quality Operations  
Specialty and Biotechnology Products

Enclosure:      Prepaid Postcard