

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

April 1, 2010

TO: All Medical Providers and Health Care Facilities

FROM: NYSDOH Bureau of Immunization

**HEALTH ADVISORY: Voluntary Recall of Prevnar® Pneumococcal 7-valent
Conjugate Vaccine**

**Please distribute to the Infection Control Department, Medical Director, Director of Nursing,
Emergency Department, Employee Health, and all patient care areas**

Wyeth Pharmaceuticals has announced a **Non-safety Related Voluntary Recall** of the Wyeth, now a part of Pfizer Inc., Prevnar® Pneumococcal 7-valent conjugate vaccine (0.5mL, for use in infants and toddlers) in pre-filled syringes that were distributed January 9, 2010- March 3, 2010.

If you have any questions regarding the information below, please contact the Wyeth Product Quality Department at 1-800-999-9384.

Summary

During a routine physical inspection of Prevnar® 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 Prevnar®. It is important to note the following key points about this recall:

- There are **NO safety concerns** with these recalled lots of Pneumococcal vaccine. All lots have successfully passed pre-release testing for purity, potency, and safety.
- Only specified lots of the Pneumococcal pediatric vaccine for children in pre-filled syringes are affected
- There is **NO NEED TO RE-ADMINISTER A DOSE** to those who received vaccine from these lots.
- All parents should continue to follow the recommended routine immunization schedule and vaccinate their children against Pneumococcal disease at 2, 4, 6, and 12-15 months of age.
- Parents of children who received vaccine from the recalled lots do not need to take any action.

- All vaccines are routinely tested for purity, potency, and safety prior to release. The four lots of vaccine meet all the required specifications at the time of release and shipment to distribution centers.

Affected Lot Numbers

Lot Number	Expiration Date	NDC#
E25197	10/13	0005-1970-50 (10's)/ 0005-1970-49 (singles)
E28211	10/13	0005-1970-50 (10's)/ 0005-1970-49 (singles)
E37556	10/13	0005-1970-50 (10's)/ 0005-1970-49 (singles)
E38749	11/13	0005-1970-50 (10's)/ 0005-1970-49 (singles)

Action Required

1. Examine your inventory to determine if you have any remaining stock of the recalled lots.
2. Please stop using the lot numbers immediately and set them aside to prevent the inadvertent administration of these lot numbers.
3. Follow the applicable instructions below to coordinate the return of the vaccine.

Instructions on How to Return Your Vaccine

1. 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 Stericycle. 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 detailed recall notice can be found at the end of this document and additional information can be found at the following link:

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/ucm206288.htm>

If you have any questions, please call the Wyeth Product Quality Department at 1-800-999-9384. Thank you for your cooperation.

WYETH

March 22, 2010

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

PRODUCT: Pevnar® Pneumococcal 7-valent Conjugate Vaccine
(Diphtheria CRM₁₉₇ 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