



Dutchess County Department of Health Public Health Advisory*

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Voluntary Recall of Pevnar Pneumococcal 7-valent conjugate vaccine

April 2, 2010 2:00 pm

Please Distribute to: Healthcare Providers, Emergency Medicine, Pediatrics, Primary Care, Internal Medicine, and Family Medicine

SUMMARY:

- ◇ Wyeth Pharmaceuticals has announced a **non-safety related voluntary recall** of four lots of Pevnar® Pneumococcal 7-valent conjugate vaccine (0.5mL, for use in infants and toddlers) in pre-filled syringes that were distributed between January 9, 2010 and March 3, 2010.
- ◇ There are **no safety concerns** with these recalled lots. All lots successfully passed pre-release testing for purity, potency, and safety.
- ◇ There is **no need to re-administer a dose** to those who received vaccine from these lots.
- ◇ For full instructions on how to return your vaccine or if you have re-distributed any of the affected lot numbers, please contact **Stericycle Inc. at 1-800-668-4391**.
- ◇ Detailed recall notice can be found at:
<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/ucm206288.htm>

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®. As a result, a voluntary recall of Wyeth Pevnar Pneumococcal 7-valent conjugate has been announced. The following table shows the list of **affected lot numbers** and their expiration date for NDC# 0005-1970-50 (10's) and 005-1970-49 (singles).

Lot Number	Expiration Date
E25197	10/13
E28211	10/13
E37556	10/13
E38749	11/13

- page one of two -

***Health Alert**- conveys the highest level of importance; warrants immediate action or attention; **Health Advisory**- provides important information for a specific incident or situation; may not require immediate action; **Health Update**- provides updated information regarding an incident or situation; unlikely to require immediate action.

Dutchess County Department of Health

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Please assure your patients that:

- ◇ 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.

Detailed recall notice can be found at the following link:

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

For further information, please call Wyeth Product Quality Control at 1-800-999-9384.