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NH-HAN 20131220



Merck Announces Gardasil® Voluntary Recall of Lot # J007354

NH Division of Public Health Services (NH DPHS) recommends:

1. Awareness of a voluntary recall of Gardasil® (Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18 Vaccine, Recombinant) Lot J007354.
2. Look for product distributed by Merck between August 20, 2013, and October 9, 2013, to public and private providers, by practices that purchased privately and through the CDC/state supplied distribution system.
3. Revaccination is not necessary. Provide additional recommended doses as previously scheduled.
4. Be sensitive to a remote risk of an injection site reaction in those who received the affected product

Background:

On December 20, 2013, the NH Division of Public Health Services was notified that Merck & Co., Inc. has initiated a voluntary recall of Gardasil® due to the potential for a limited number of vials to contain glass particles. This lot was distributed by Merck between August 20, 2013, and October 9, 2013. CDC/state supplied vaccine was distributed during the first two weeks of October. No other distributed lots of Merck product are affected.

The recall was initiated due to the potential for a small number of vials to contain glass particles as a result of breakage during the manufacturing process. There were 743,360 vials in the affected lot. Merck estimates that approximately ten of those vials could have glass particles in them. If a vaccine containing glass particles was administered to a patient, there is a remote risk of an injection site reaction. Merck reports that the sterility of the vaccine has not been impacted.

If the product from this lot has been administered, revaccination is not necessary. Continue with the vaccination series as recommended.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Please examine your inventory and quarantine (set aside and mark) all Gardasil® vaccine - lot J007354. If Merck has shipped this lot number to your practice, will give guidance regarding the return of the vaccine.

- ▶ For questions about this recall or to report any adverse events following vaccination, please contact: Merck National Service Center: 800-672-6372 Select Prompt #2 then Prompt #3 (Monday to Friday 8:00 am to 7:00 pm EST).
- ▶ For any questions regarding the contents of this message, please contact NH DHHS, DPHS, Bureau of Infectious Disease Control Immunization Section at 603-271-4482 during business hours.
- ▶ To change your contact information in the NH Health Alert Network, contact Denise Krol at 603-271-4596 or email Denise.Krol@dhhs.state.nh.us

Status: Actual
Message Type: Alert
Severity: Moderate
Sensitivity: Not Sensitive
Message Identifier: NH-HAN 20131220 Gardasil® Voluntary Recall of Lot # J007354
Delivery Time: 12 hours
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Distribution Method: Email, Fax
Distributed to: Physicians, Physician Assistants, Practice Managers, Infection Control Practitioners, Infectious Disease Specialists, Community Health Centers, Hospital CEOs, Hospital Emergency Departments, Nurses, NHHA, Laboratory Response Network, Manchester Health Department, Nashua Health Department, Public Health Network, DHHS Outbreak Team, DPHS Investigation Team, DPHS Management Team, Northeast State Epidemiologists
From: José T. Montero, MD, MHCDS – Director of Public Health Services
Originating Agency: NH Department of Health and Human Services, Division of Public Health Services

Attachments: None