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May 16, 2011

Dear Healthcare Professional,

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., would like to reinforce the importance of examining all vaccines and ANTIVENIN™ (Latrodectus mactans) products for particulate matter and discoloration prior to use. We have observed in very rare cases – a reported rate of less than 1 in 6 million overall vials -- that vials of our vaccine and ANTIVENIN™ products may contain brown particles. Our investigation and testing identified that these particles were derived from the plastic packaging used to cover empty vials during shipment to Merck. Small pieces of this inert carbon material can adhere to the inside of product vials and turn a brown color during the sterilization process. There is no impact expected to the sterility or the potency of the vaccines and ANTIVENIN™ from this particulate matter. However, vaccines and ANTIVENIN™ containing small quantities of particulate matter may potentially lead to injection-site reactions if the material is not noticed prior to injection.

Prior to their filling with the vaccine or ANTIVENIN™ preparation, the storage vials go through an intensive cleaning and sterilization process. As part of our quality control systems, we have inspection systems to detect and remove vials containing particles. However, in these rare instances, the adherent particles were not detected or removed by our quality assurance and inspection systems.

Merck remains committed to ensuring the quality of our products. We have already begun to take further steps to eliminate this potential source of particle introduction. We continuously look for additional opportunities to eliminate potential sources for particle introduction into our manufacturing processes, including this specific material.

Vaccines and ANTIVENIN™ should always be inspected for particulate matter and discoloration prior to use. If you receive a vial of a Merck vaccine or ANTIVENIN™ containing particles, please set aside the vial and contact the Merck National Service Center at the number below. Please note that vaccines supplied in prefilled syringes and oral dosing tubes are not impacted by this issue.

A list of all injectable vaccines and ANTIVENIN™ manufactured by Merck that may be affected by this issue is attached at the end of this letter.

If you have any questions about our vaccines or ANTIVENIN™, or to report any suspected adverse events, please contact the Merck National Service Center at (800) 444-2080. Suspected adverse events should also be reported to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (www.vaers.hhs.gov) for vaccine products or MedWatch at (800) 332-1088 (www.fda.gov/medwatch) for ANTIVENIN™.

Sincerely,

Mark Feinberg, MD, PhD

Vice President and Chief Public Health and Science Officer, Merck Vaccines

 $\mathsf{COMVAX}^{\otimes}$ [Haemophilus b conjugate (meningococcal protein conjugate) and hepatitis B (recombinant) vaccine]

GARDASIL® [human papillomavirus quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant]

M-M-R[®] II [measles, mumps and rubella virus vaccine live]

PEDVAX ${\sf HIB}^{\it \&}$ [Haemophilus b conjugate vaccine (meningococcal protein conjugate)]

PNEUMOVAX® 23 [pneumococcal vaccine polyvalent]

PROQUAD® [measles, mumps, rubella and varicella virus vaccine live]

RECOMBIVAX HB® [hepatitis B vaccine (recombinant)]

VAQTA® [hepatitis A vaccine, inactivated]

VARIVAX® [varicella virus vaccine live]

ZOSTAVAX[®] [zoster vaccine live]

ANTIVENIN™ (Latrodectus mactans)