



THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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**FDA and CDC Issue Alert on Menactra Meningococcal Vaccine
and Guillain Barre Syndrome**

The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are alerting consumers and health care providers to five reports of Guillain Barre Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature.

Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization.

Meningococcal infection, which Menactra prevents, is a major cause of bacterial meningitis, affecting approximately 1 in 100,000 people annually. The infection can be life threatening: 10-14 percent of cases are fatal and 11-19 percent of survivors may have permanent disability.

According to Jesse Goodman, MD, Director of FDA's Center for Biologics Evaluation and Research, at the present time there are no changes in recommendations for vaccination; individuals should continue to follow their doctors' recommendations. FDA and CDC are not able to determine if any or all of the cases were due to vaccination. The current information is very preliminary and the two agencies are continuing to evaluate the situation.

Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. Individuals can report to VAERS on the web at www.vaers.hhs.gov or by phone at 1-800-822-7967.

The five cases of GBS reported following administration of Menactra occurred in individuals living in NY, OH, PA, and NJ. All five patients were 17 or 18 years of age and developed weakness or abnormal sensations in the arms or legs, two-four weeks after vaccination. All individuals are reported to be recovering or to have recovered. More than 2.5 million doses of Menactra vaccine have been distributed to date. The rate of GBS based on the number of cases reported following administration of Menactra is similar to what might have been expected to occur by coincidence, that is, even without vaccination. However, the timing of the events is of concern. Also, vaccine adverse events are not always reported to FDA so there may be additional cases of which we are unaware at this time.

Prelicensure studies conducted by Sanofi Pasteur of more than 7000 recipients of Menactra showed no GBS cases. CDC conducted a rapid study using available health care organization databases and found that no cases of GBS have been reported to date among 110,000 Menactra recipients.

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