

October 18, 2002

**Medical Statement on the Voluntary Recall of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) single-dose vials, Lots UB040AA (Expiration date 7/25/03), UB040AB (Expiration date 8/14/03), UB070AA (Expiration date 9/26/03) and UB096AA (Expiration date 9/28/03)**

**Voluntary Withdrawal of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) in single-dose vials (see addendum for lot numbers)**

Aventis Pasteur recently completed a routine 12-month stability test of retained samples of Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined) in single-dose vials. The potency test result for lots UB040AA, UB040AB, UB070AA and UB096AA for serogroup A failed the specification for this test. This result indicates a potential for reduced protection against disease caused by serogroup A. This failure does not affect the vaccine's efficacy against disease caused by serogroups C, Y, or W-135, which are present in the U.S. To the best of our knowledge, serogroup A does not circulate in the U.S. (Centers for Disease Control and Prevention maintains nationwide active and passive surveillance for meningococcal disease and has identified only one serogroup A case in the last 10 years).

Aventis Pasteur initiated the voluntary withdrawal as a precautionary measure because single-dose vials of Menomune®-A/C/Y/W-135 may fail potency standards for serogroup A before the expiration date. The vaccine met specifications at the time of release and it is our assessment that the vaccine was potent for at least six months after release.

We believe that most product from the recalled and withdrawn lots was used within six months of release. Furthermore, a recent clinical trial using a related lot of Menomune®-A/C/Y/W-135, administered to adults four to six months after lot release, demonstrated protection against serogroup A. Therefore, it is likely that those who received vaccine from the recalled and withdrawn lots are protected against serogroup A.

To the best of our knowledge, serogroup A does not circulate in the U.S. (Centers for Disease Control and Prevention maintains nationwide active and passive surveillance for meningococcal disease and has identified only one serogroup A case in the last 10 years). The vast majority of Menomune®-A/C/Y/W-135 is administered to college students and others not traveling to countries where serogroup A disease is present.

A number of states have passed legislation requiring colleges and universities to provide their students with information about meningococcal disease and access to immunization. These recommendations were based on an increased risk of serogroup C disease in college freshmen who live in dormitories. U.S. college students should not be at risk for serogroup A disease unless they travel to countries that pose a high risk for contracting serogroup A *Neisseria meningitidis*.

Revaccination with Menomune®-A/C/Y/W-135 for protection against serogroup A disease should be considered for persons vaccinated since January 2, 2001 and who have laboratory or industrial exposure to serogroup A or who travel to certain parts of the world. Serogroup A is responsible for epidemic and endemic meningococcal disease in the African “meningitis belt,” which includes parts of Benin, Burkina Faso, Cameroon, Chad, Ethiopia, Gambia, Ghana, Mali, Niger, Nigeria, Senegal and Sudan.<sup>1</sup> In addition, serogroup A epidemics have occurred in Burundi, Rwanda, and the United Republic of Tanzania.<sup>2</sup> Outbreaks have also occurred in association with the annual Hajj pilgrimage in Saudi Arabia.<sup>3</sup> Periodically, epidemic serogroup A meningococcal disease occurs in other regions of the world. Information about geographic regions where serogroup A meningococcal disease is present can be found at [www.cdc.gov/travel](http://www.cdc.gov/travel).

Very truly yours,



James Froeschle, M.D.  
Director, Scientific & Medical Affairs

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<sup>1</sup> Health Information for International Travel, Center for Disease Control and Prevention, 2001-2002

<sup>2</sup> Communicable Disease Surveillance and Response (CSR), *WHO*: September 4, 2002

<sup>3</sup> Communicable Disease Surveillance and Response (CSR), *WHO*: April 20, 2000