WYETH-LEDERLE VACCINES & PEDIATRICS

PO Box 8229, Philadelphia, PA 19101-8299 - (610) 688-4400 Division of American Home Products Corporation

IMPORTANT PRODUCT WITHDRAWAL
RotaShield® Rotavirus Vaccine

October 14, 1999

Dear Healthcare Provider:

This letter is to inform you of our decision to withdraw from distribution and to request the immediate return of all RotaShield® Rotavirus Vaccine, Live, Oral, Tetravalent.

On July 16, 1999, Wyeth Lederle Vaccines temporarily suspended further distribution and administration of RotaShield® until more data on the potential association between vaccine administration and intussusception became available. That action was taken in consultation with the Food and Drug Administration (FDA) following a recommendation from the Centers for Disease Control and Prevention (CDC) to postpone administration because of reports to the Vaccine Adverse Events Reporting System (VAERS) of a possible association between the use of RotaShield® and the development of intussusception.

At that time, it was hoped that conclusive data would become available before the 1999-2000 rotavirus season. We have evaluated the additional cases of intussusception reported to VAERS as well as preliminary data from the ongoing epidemiological studies conducted by CDC; these data will be publicly discussed at the upcoming Advisory Committee on Immunization Practices (ACIP) meeting on October 22, 1999. These data continue to suggest a temporal association between the use of RotaShield® and the development of intussusception. While additional studies are planned or in progress to better understand this relationship, we believe that the use of RotaShield® should not be resumed during the upcoming rotavirus season.

Therefore, Wyeth Lederle Vaccines believes it is in the best interest of the public and our customers for the company to withdraw all remaining supplies of the vaccine.

It is important to note that available data do not indicate an ongoing risk to children given RotaShield® in the past.

Upon receipt of this letter, we request immediate return of all RotaShield® inventories. Within the next few days customers will receive a returns shipping label and instructions for the prepaid return of all product to:

Pharmacy Solutions, Inc.
2084-M Lake Industrial Court
P.O. Box 998 (30012)
Conyers, GA 30013
800-777-6565

A handling charge will be credited to your account. Full credit will be given for each single-dose unit returned. Wyeth Lederle sales representatives are available to assist you with any return needs.

You and your patients may call 1-877-ROTA-KID (1-877-768-2543) with any questions.

Sincerely,

Harold K. Marder, M.D., FAAP
Senior Vice President and Medical Director