URGENT: VACCINE RECALL

12-Jun-2012

Dear Customer:

This is to inform you of a voluntary product recall of:

M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live), Lot 0851AA

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (Merck), is initiating this voluntary recall due to the inadvertent shipment of doses from Lot 0851AA of M-M-R® II to customers. These doses were distributed by Merck between May 17, 2012 and May 25, 2012. This recall is due to a unique event caused by human error, resulting in distribution of the product prior to completing a secondary visual inspection of the lot prior to release.

Our comprehensive investigation concluded that there are no product safety, quality, or efficacy concerns associated with the use of this lot. If product from this lot has been administered, revaccination is not necessary. However, as a conservative measure, Merck is initiating a voluntary recall of lot 0851AA because it was not released in accordance with Merck's internal batch release procedures. The supply of M-M-R® II will not be impacted by this recall. Lot 0851AA of M-M-R® II is the only lot impacted by the recall and was distributed solely within the United States.

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

Please examine your inventory immediately and quarantine all product from lot 0851AA.

- Please return the vaccine according to the procedure described below.
- If you have further distributed material from this lot, please conduct a sub-recall and notify your customer of this product recall, as described on the next page.

In order to ensure an effective recall and return process, it is important that you do the following:

1. Please complete the enclosed Business Reply Card and the Packing Slip, including the entry of number of cartons / vials returned.
2. Mail the postage paid Business Reply Card, even if you do not have any of the product identified above to ensure accountability.
3. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

   Stericycle, Inc.
   Attn: Event 4052
   2670 Executive Drive, Suite A
   Indianapolis, IN 46241

For product that has been further distributed:

1. Please notify customers who received M-M-R® II (Measles, Mumps, and Rubella Virus Vaccine Live) lot 0851AA and request that they immediately examine their inventory and quarantine all product from this lot. Notification to these customers must include a copy of:
   - this "Dear Customer Letter" and
   - the Notification of Vaccine Recall (attached)

2. Instruct the customer to contact Stericycle, Inc. at 888-257-7904 for product return instructions. Prepaid packing slips and business reply cards will be provided to all customers by Stericycle, Inc.

Reimbursement for product returned under this recall will be issued as credit or check, based upon Merck's determination.

Please complete and return the enclosed response form as soon as possible.

For questions about this recall, please contact:
Merck National Service Center: 800-672-6372 (Monday to Friday 8 AM to 7 PM EST)

For questions about the recall process, please contact:
Stericycle, Inc.: 888-257-7904

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.

Elaine S. Perry, MD, MS
Office of the Chief Medical Officer