North Carolina Department of Health and Human Services
Division of Public Health

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Daniel Staley
Acting Division Director

December 20, 2013

MEMORANDUM

TO: Select North Carolina Immunization Program (NCIP) Providers

FROM: Wendy Holmes, RN, Acting Head WH
Immunization Branch

RE: GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18)] Vaccine
Recall of Lot J007354

The purpose of this memo is to provide notification that your practice has received vaccine from a lot of GARDASIL® that is being voluntarily recalled by the manufacturer, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (Merck). This recall is being conducted with the knowledge of the Food and Drug Administration.

Merck is initiating this voluntary recall due to a limited number of vials of lot J007354 potentially containing glass particles. This lot, J007354, was distributed by Merck between August 20, 2013 and October 9, 2013. GARDASIL® lot J007354 is the only lot impacted by the recall and was distributed solely within the United States. At this time, there is adequate inventory to replace the recalled product.

Providers should immediately discontinue administering GARDASIL® from this lot. Providers should quarantine (that is, remove from the refrigerator) any remaining vaccine from GARDASIL® lot J007354, and label it "**DO NOT USE**". It is not necessary to refrigerate quarantined vaccine. If product from this lot has been administered, revaccination is ***not*** necessary. If a vaccine containing glass particles is administered to a patient, there is a remote risk of an injection site reaction. The sterility of the vaccine has not been impacted. Any remaining vaccine from this lot should be returned according to the instructions from Merck (attached).

If you are a North Carolina Immunization Registry (NCIR) user, please subtract any remaining doses of GARDASIL® lot number J007354 in the NCIR through the "modify quantity" function. Choose the category "wasted doses" and indicate the reason wasted and preventive action as "VACCINE RECALL."

Questions regarding this vaccine recall should be addressed to the NCIR Help Desk at 1-877-873-6247.

CC: SMT Regional Immunization Staff
Terri Pennington
Joy Reed
Central Office Staff
Frank Skwara
Gregg Griggs
Vaccine Manufacturers
Lisa Weeks
Ann Nichols
Steve Shore
Jason Swartz
Peter Graber
Taryn Edwards

URGENT: VACCINE RECALL

XX-Dec-2013

Dear Customer:

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

GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant],
Lot J007354

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (Merck), is initiating this voluntary recall due to the potential for a limited number of vials to contain glass particles. This lot was distributed by Merck between August 20, 2013 and October 9, 2013. No other distributed lots of Merck product are affected.

Our investigation concluded that for certain vials in the affected lot, the potential exists for small glass particles to be present in the vial. If a vaccine containing glass particles is administered to a patient, there is a remote risk of an injection site reaction. The sterility of the vaccine has not been impacted.

If product from this lot has been administered, revaccination is not necessary. The supply of GARDASIL® will not be impacted by this recall. GARDASIL® Lot J007354 is the only lot impacted by the recall and was distributed solely within the United States, including Puerto Rico. There is adequate inventory to replace recalled product at this time.

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

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

1. Please examine your inventory and quarantine all vaccine from GARDASIL® lot J007354.

    - 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 direct customers of this product recall, as described on the next page.

2. Please complete the enclosed Business Reply Card and the Packing Slip labeled “Non-VFC (Vaccines For Children) or Non-CDC Vaccine”, including the entry of number of cartons / vials returned.

3. Mail the postage paid Business Reply Card, **even if you do not have any of the product identified above** to ensure accountability.

4. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

Stericycle, Inc.
Attn: Event 6553
2670 Executive Drive, Suite A
Indianapolis, IN 46241

For any Vaccines for Children (VFC) vaccine from Lot J007354, please do the following:

1. Please complete the Business Reply Card and the Packing Slip labeled “VFC (Vaccines For Children) or CDC Vaccine” ”, 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 Label to:

Stericycle, Inc.
Attn: Event 6553
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you have both Non-VFC / Non-CDC and VFC / CDC vaccine to return, you may ship them together in the same shipping container as long as you have accounted for the vials separately using the appropriate forms outlined above.

<u>For product that has been further distributed:</u>

- Please notify any direct customers to whom you distributed GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], Lot J007354, and request that they immediately examine their inventory and quarantine all vaccine from this lot. Please include a copy of the following in the notification to these customers:

  - this "Dear Customer Letter" and
  - the Notification of Vaccine Recall (attached)

- Instruct the customers to contact Stericycle, Inc. at 855-741-4996 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 Business Reply Card as soon as possible.

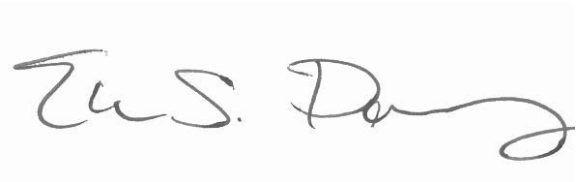
For questions about the recall process (including how to return the recalled product and getting reimbursed for returned product), please contact:

- Stericycle, Inc.: 855-741-4996

For questions about this recall or to report any adverse events following vaccination, please contact:

- Merck National Service Center: 800-672-6372 Select Prompt #2 then Prompt #3. (Monday to Friday 8:00 AM to 7:00 PM EST)

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