



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY, M.D.
COMMISSIONER

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TTY: 1-800-735-2989
www.dshs.state.tx.us

TO: Texas Vaccines for Children (TVFC) Providers

FROM: Saroj Rai, Ph.D. 
Immunization Branch Manager

DATE: December 20, 2013

SUBJECT: VOLUNTARY VACCINE RECALL FOR GARDASIL®

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 & Co., Inc. 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.

Merck's 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. There is adequate inventory to replace recalled product at this time.

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.
2. Please see the attached letter from Merck for additional information regarding return of the affected product.

3. If you have further distributed material from this lot, please conduct a sub-recall. Notify your direct customers of this product recall, 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)

If you have questions about the recall process (including how to return the recalled product and getting reimbursed for returned product), please contact your DSHS Health Service Region or TVFC Regional Consultant. The Regional Consultant contact information is included below.

Health Service Region	Consultant	Phone	Email
Region 1, 4/5N, 6/5S, and 7	Joshua Hay	(512) 776-6496	Joshua.Hay@dshs.texas.gov
Region 8, 11, 25, and 00 (City of Houston and City of San Antonio)	Alma Chavez	(956) 421-5554	Alma.Chavez@dshs.texas.gov
Region 2, 3, 9, and 10	Shirley Rocha	(512) 776-3417	Shirley.Rocha@dshs.texas.gov

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.

For product that has been further distributed:

- 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.

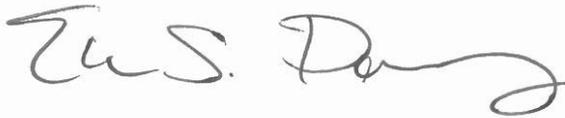
For questions about the recall process (including how to return the recalled product and getting reimbursed for returned product), please contact:

- 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.

A handwritten signature in black ink, appearing to read "E.S. Perry". The signature is fluid and cursive, with a long horizontal stroke at the end.

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

VFC (Vaccines For Children) or CDC Vaccine

Use other BRC for Non-VFC or Non-CDC Vaccine

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

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10X Cartons to be Returned	Number of Vials from Partial Cartons to be Returned
Vial Label: 0006-4045-01 Carton Label: 0006-4045-41	10 single dose (0.5mL) vials in 1 carton	J007354	February 20, 2016		

**Merck Sharp &
Dohme Corp.**

GARDASIL®

December XX, 2013

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, **even if you do not have the recalled product.** Thank you.

Signature _____ Title _____

Name _____ Phone _____

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

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10X Cartons Returned	Number of Vials from Partial Cartons Returned
Vial Label: 0006-4045-01 Carton Label: 0006-4045-41	10 single dose (0.5mL) vials in 1 carton	J007354	February 20, 2016		

**Merck Sharp &
Dohme Corp.**

GARDASIL®

December XX, 2013

The following information is required to assure proper crediting:

Debit Memo (optional): _____

Firm Name: _____

Address: _____

Non-VFC (Vaccines For Children) or Non-CDC Vaccine

Use other BRC for VFC or CDC Vaccine

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

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10X Cartons to be Returned	Number of Vials from Partial Cartons to be Returned
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Merck Sharp & Dohme Corp.

GARDASIL®

December XX, 2013

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, **even if you do not have the recalled product.** Thank you.

Signature _____ Title _____

Name _____ Phone _____

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

PACKING SLIP

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10X Cartons Returned	Number of Vials from Partial Cartons Returned
Vial Label: 0006-4045-01 Carton Label: 0006-4045-41	10 single dose (0.5mL) vials in 1 carton	J007354	February 20, 2016		

Merck Sharp & Dohme Corp.

GARDASIL®

December XX, 2013

The following information is required to assure proper crediting:

Debit Memo (optional): _____

Firm Name: _____

Address: _____

Merck Account Number: _____

If ordered through a wholesaler or distributor, please indicate wholesaler or distributor name in space provided.

Wholesaler/Distributor Name: _____