



TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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COMMISSIONER

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TO: Texas Vaccines for Children (TVFC) Providers

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

DATE: December 4, 2013

SUBJECT: TVFC: Meningococcal Conjugate Vaccine Recall from Novartis

Novartis Vaccines is implementing a voluntary market recall of one lot of MENVEO® Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM-197 Conjugate Vaccine. This precautionary and voluntary action is being taken following observation of higher-than-specified levels of residual moisture within the lyophilized MenA component vial in the lot noted below:

Lot # M12115 (Men A vial Lot # A12115 and Men CWY vial lot # X12115)

Novartis Vaccines is not aware of any safety issues that could arise due to higher moisture content. **It is important to note that no action is required for patients previously vaccinated with a dose from this lot.** Please see the attached letter from Novartis Vaccines for more information.

The Centers for Disease Control and Prevention (CDC) has indicated that the lot in question was distributed only in the private sector, and Novartis is working directly with the customers who purchased the vaccine regarding the recall.

If you have questions, 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 (City of Houston), and 00 (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

IMPORTANT NOTICE REQUIRING IMMEDIATE ATTENTION

**MENVEO® Meningococcal (Groups A, C, Y and W-135) Oligosaccharide
Diphtheria CRM₁₉₇ Conjugate Vaccine
NDC: 46028-208-01**

RE: Notification of Voluntary Market Recall of MENVEO Lot # M12115

December 2, 2013

Dear Customer:

I wish to inform you that Novartis Vaccines is implementing a voluntary market recall of one Lot of MENVEO® Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM₁₉₇ Conjugate Vaccine. This precautionary and voluntary action is being taken following observation of higher-than-specified levels of residual moisture within the lyophilized MenA component vial in the Lot noted below. This residual moisture content is not expected to impact product quality, but constitutes a deviation to registered specifications. All other aspects of this Lot have met the required quality standards.

Novartis Vaccines is not aware of any safety issues that could arise due to higher moisture content. **It is important to note that no action is required for patients previously vaccinated with a dose from this Lot.**

According to our records, you have purchased doses of MENVEO directly from Novartis Vaccines. We request that you check your inventory of MENVEO to determine if you have any product with the following Lot number:

Lot # M12115 (Men A vial Lot # A12115 and Men CWY vial Lot # X12115).

Only MENVEO vials with the above specified Lot numbers are subject to this market recall; all other MENVEO Lots are unaffected and may continue to be used.

If you have doses on hand from this Lot, please follow the steps outlined on the next page on how to manage the return of the affected product to Novartis Vaccines.

Novartis Vaccines has communicated about this voluntary and precautionary action with the U.S. Food and Drug Administration.

We appreciate your immediate attention to this notice and sincerely regret any inconvenience this has caused.

If you have any additional questions or concerns, please contact 1-877-NV-DIRECT (1-877-683-4732) and select option 3.

Regards,



Clement S. Lewin PhD MBA
Vice President, Head Medical Affairs and Immunization Policy
Novartis Vaccines

**MENVEO® Meningococcal (Groups A, C, Y and W-135) Oligosaccharide
Diphtheria CRM₁₉₇ Conjugate Vaccine
NDC: 46028-208-01**

Process to Return Doses/Boxes of MENVEO from Lot # M12115 Purchased from Novartis Vaccines

If you purchased doses of MENVEO directly from Novartis Vaccines, and have doses on hand from Lot # M12115, please follow the steps outlined below in order to return this product free of charge to Novartis Vaccines to obtain an **invoice credit for replacement product**.

1. Verify that the product is labeled with the Lot # M12115.
2. **Complete and return the enclosed Business Reply Card and indicate how many unused doses you have on hand that are impacted by this market recall. *Please complete this card even if you have no doses on hand.***
3. If you have doses on hand, please contact Novartis Vaccines Customer Service at 1-877-NV-DIRECT (1-877-683-4732). Select option 3 for a Return Goods Authorization (RGA) and follow instructions regarding return of the vaccine.
4. Use the enclosed UPS shipping label to return any unused doses. Please note that cold transport is **not required** for returned goods.

If you have any questions regarding this process, please contact Novartis Vaccines Customer Service at 1-877-NV-DIRECT (1-877-683-4732) and select option 3.

For any questions of a medical nature, please call Novartis Vaccines Medical Communications at 1-877-NV-DIRECT (1-877-683-4732) and select option 1.