



## TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY, M.D.  
COMMISSIONER

P.O. Box 149347  
Austin, Texas 78714-9347  
1-888-963-7111  
TTY: 1-800-735-2989  
[www.dshs.state.tx.us](http://www.dshs.state.tx.us)

**TO:** Texas Vaccines for Children (TVFC) Providers

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

**DATE:** July 11, 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 # M12118 (Men A vial Lot # A12118 and Men CWY vial lot # X12118)**

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.**

Novartis Vaccines will send instructions to each TVFC provider that received a shipment of the effected lot of MENVEO®. TVFC providers should follow the instructions that are provided to them for replacement of doses.

TVFC providers who send in recalled doses should not report the doses as a loss. Once the doses have been sent to Novartis, providers should account for the reduced inventory using the C-33 Reconciliation page in the Electronic Vaccine Inventory (EVI) system. Use the drop down to select "Recall/Replacement" as the reason for having fewer doses on hand than calculated. Once replacement doses are received, providers should include the new doses in their inventory using Add Line.

If you have questions, please contact your DSHS Health Service Region or TVFC Regional Consultant. The Regional Consultant contact information is included below.

<b>Health Service Region</b>	<b>Consultant</b>	<b>Phone</b>	<b>Email</b>
Region 1, 4/5N, and 7	Joshua Hay	(512) 776-6496	<a href="mailto:Joshua.Hay@dshs.texas.gov">Joshua.Hay@dshs.texas.gov</a>
Region 6/5S, 9, and 25 (City of Houston)	Shyla Delp	(512) 776-6333	<a href="mailto:Shyla.Delp@dshs.texas.gov">Shyla.Delp@dshs.texas.gov</a>
Region 8, 11, and 00 (City of San Antonio)	Alma Chavez	(956) 421-5554	<a href="mailto:Alma.Chavez@dshs.texas.gov">Alma.Chavez@dshs.texas.gov</a>
Region 2, 3, and 10	Shirley Rocha	(512) 776-3417	<a href="mailto:Shirley.Rocha@dshs.texas.gov">Shirley.Rocha@dshs.texas.gov</a>

**IMPORTANT NOTICE REQUIRING IMMEDIATE ATTENTION**

**MENVEO® Meningococcal (Groups A, C, Y and W-135) Oligosaccharide  
Diphtheria CRM-197 Conjugate Vaccine  
NDC: 46028-208-01**

**RE: Notification of Voluntary Market Recall of MENVEO lot # M12118**

July 3, 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 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. 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 either purchased doses of MENVEO directly from Novartis Vaccines or have been provided doses of MENVEO through your state or local immunization program.

We request that you check your inventory of MENVEO to determine if you have any product with the following lot number:

**Lot # M12118 (Men A vial Lot # A12118 and Men CWY vial lot # X12118).**

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 CRM-197 Conjugate Vaccine  
NDC: 46028-208-01**

**Process to Return Doses/Boxes of MENVEO from Lot # M12118 Purchased from Novartis Vaccines**

If you purchased doses of MENVEO directly from Novartis Vaccines, and have doses on hand from lot # M12118, 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 # M12118.
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.

**MENVEO® Meningococcal (Groups A, C, Y and W-135) Oligosaccharide  
Diphtheria CRM-197 Conjugate Vaccine  
NDC: 46028-208-01**

**Process to Return Doses/Boxes of MENVEO from lot # M12118 Provided Through State or Local Immunization Programs**

If you have been provided doses of MENVEO through your state or local immunization program and have doses on hand from lot # M12118, please follow the steps outlined below in order to return this product free of charge to Novartis Vaccines to obtain a **shipment of replacement product**.

1. Verify that the product is labeled with the lot # M12118.
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. You will also be asked to provide the number of unused doses provided through your state or local immunization program so that a replacement shipment can be sent directly to you from Novartis Vaccines.
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.

MENVEO® Meningococcal (Groups A,C,Y and W-135) Oligosaccharide Diphtheria CRM-197 conjugate vaccine			
NDC Number	Lot Number	Expiration Date	Number of Doses Being Returned
46028-208-01	M12118 <i>Sub lots: X12118 and A12118</i>	31-AUG-2014	

**BUSINESS REPLY CARD**

Novartis Vaccines  
Recall Program  
July 9, 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.

- We have stock of the recalled product listed above and will be returning the number of doses shown.
- We do not have any stock of the above recalled product and will not be making a return.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Contact Name: \_\_\_\_\_ Phone #: \_\_\_\_\_

ID # G14495000074921901



MENVEO® Meningococcal (Groups A,C,Y and W-135) Oligosaccharide Diphtheria CRM-197 conjugate vaccine			
NDC Number	Lot Number	Expiration Date	Number of Doses Being Returned
46028-208-01	M12118 <i>Sub lots: X12118 and A12118</i>	31-AUG-2014	

**PACKING SLIP**

Novartis Vaccines  
Recall Program  
July 9, 2013

Contact Name: \_\_\_\_\_ Phone #: \_\_\_\_\_

ID # G14495000074921901



G14495000074921901

1 LBS 1 OF 1

RS

**SHIP TO:**  
GENCO PHARMACEUTICAL  
SERVICES  
(414)-967-2800  
6101 NORTH 64TH STREET  
MILWAUKEE WI 53218

WI 532 9-30

UPS GROUND

TRACKING #: 1Z 58R 310 90 0933 0098

DESC: LETTER    Event #: G14495  
RETURN SERVICE  
Reference No. 1: CA01G144950000

39.5A 04/2013

**PACKING INSTRUCTIONS**

- Regardless of whether there is product to return or not, please fill out the prepaid BRC (top portion of this page), separate at the perforation, and return via U.S. Mail.
- If there is product to return, please fill out the Packing Slip (middle portion of this page), photocopy for your records, and include the original packing slip inside the box with your product shipment.
- Properly package product to prevent breakage. Peel off the UPS label and affix to shipping box. Give shipment directly to any UPS driver or deliver to a UPS office or drop box (Do not enter this shipment in your UPS log book or apply any other UPS shipping label or bar code). Product should be shipped at ambient temperature. Cold packs are not required.

MENVEO® Meningococcal (Groups A,C,Y and W-135) Oligosaccharide Diphtheria CRM-197 conjugate vaccine			
NDC Number	Lot Number	Expiration Date	Number of Doses Being Returned
46028-208-01	M12118 <i>Sub lots: X12118 and A12118</i>	31-AUG-2014	

BUSINESS REPLY CARD

Novartis Vaccines  
Recall Program  
July 9, 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.

- We have stock of the recalled product listed above and will be returning the number of doses shown.
- We do not have any stock of the above recalled product and will not be making a return.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Contact Name: \_\_\_\_\_ Phone #: \_\_\_\_\_

ID # G14495000074922001



MENVEO® Meningococcal (Groups A,C,Y and W-135) Oligosaccharide Diphtheria CRM-197 conjugate vaccine			
NDC Number	Lot Number	Expiration Date	Number of Doses Being Returned
46028-208-01	M12118 <i>Sub lots: X12118 and A12118</i>	31-AUG-2014	

PACKING SLIP

Novartis Vaccines  
Recall Program  
July 9, 2013

Contact Name: \_\_\_\_\_ Phone #: \_\_\_\_\_

ID # G14495000074922001



G14495000074922001

1 LBS 1 OF 1

**RS**

**SHIP TO:**  
GENCO PHARMACEUTICAL SERVICES  
(414)-967-2800  
6101 NORTH 64TH STREET  
MILWAUKEE WI 53218

**WI 532 9-30**

**UPS GROUND**  
TRACKING #: 1Z 58R 310 90 0933 0105

DESC: LETTER RETURN SERVICE  
Event #: G14495  
Reference No. 1: CA01G144950000

39.5A 04/2013

PACKING INSTRUCTIONS

- Regardless of whether there is product to return or not, please fill out the prepaid BRC (top portion of this page), separate at the perforation, and return via U.S. Mail.
- If there is product to return, please fill out the Packing Slip (middle portion of this page), photocopy for your records, and include the original packing slip inside the box with your product shipment.
- Properly package product to prevent breakage. Peel off the UPS label and affix to shipping box. Give shipment directly to any UPS driver or deliver to a UPS office or drop box (Do not enter this shipment in your UPS log book or apply any other UPS shipping label or bar code). Product should be shipped at ambient temperature. Cold packs are not required.