# Medical Material Quality Control Message MMQC-15-2022

Message Number: MMQC-15-2022

Released On: 24-NOV-15
Message Class: Informational

Material Type: Vaccine

MMQC\MMI Reference: FDA Recall Reference: ECRI Reference: DLA Reference:

MFG Release Date: 11-NOV-2015

## **Subject:**

Adenovirus Type 4 and Type 7 Vaccine / Teva Women's Health, Inc.

## **Reason / Information:**

Teva Women's Health issued information on the 36 month expiration of Adenovirus Type 4 and Type 7 Vaccine, Live, Oral (See Image on Message under Additional Documentation/Attachment). Reason: Completion of the 36 stability studies on Adenovirus Type 4 and Type 7 Vaccine, Live, Oral.

# **Disposition / Instructions:**

This stability data was submitted to the FDA in a Prior Approval Supplement on 6 February 2015. On 5 June 2015, the FDA approved the extension of the vaccine expiration date from 30 months to 36 months. Approval of the expiration date extension is applicable to all commercial vaccine batches including those batches that were manufactured prior to the expiration date extension as those batches were manufactured and tested by the same commercially approved process. The following batches/carton lot numbers are impacted (See Image on Message under Additional Documentation/Attachment).

## **Item Information:**

NSN (FSC-NIIN): 6505 - 016420106

Nomenclature: ADENOVIRUS TYPE 4 AND TYPE 7 VACCINE, LIVE, ORAL

UI: PG

**Manufacturer:** TEVA WOMEN'S HEALTH, INC.

Distributor:

#### LOT / SN:

346000863460008834600122 346001233460012434600125 346001343460013534600149 346001503460016134600175 346001763460017734600186 346001873460019934600209 346002103460021234600244 346002453460024634600254 34600266

#### NOTE 1:

Lot #34600086 - New Expiration Date - April 2015; Lot #34600088 - New Expiration Date - March 2015; Lot #34600122 - New Expiration Date - August 2015; Lot #34600124 - New Expiration Date - October 2015; Lot #34600123 - New Expiration Date - April 2015; Lot #34600125 - New Expiration Date - November 2015; Lot #34600134 - New Expiration Date - October 2015; Lot #34600135 - New Expiration Date - January 2016; Lot #34600149 - New Expiration Date - March 2016; Lot #34600150 - New Expiration Date - March 2016; Lot #34600161 - New Expiration Date - June 2016; Lot #34600175 - New Expiration Date - July 2016; Lot #34600176 - New Expiration Date - August 2016; Lot #34600177 - New Expiration Date - August 2016; Lot #34600186 - New Expiration Date - March 2016; Lot #34600187 - New Expiration Date - October 2016; Lot #34600199 - New Expiration Date - November 2016; Lot #34600209 - New Expiration Date - January 2017; Lot #34600210 - New Expiration Date - January 2017; Lot #34600244 - New Expiration Date - June 2017; Lot #34600245 - New Expiration Date - June 2017; Lot #34600254 - New Expiration Date - June 2017; Lot #34600254 - New Expiration Date - June 2017; Lot #34600254 - New Expiration Date - January 2018

NSN (FSC-NIIN): 6505 - 015780003

Nomenclature: ADENOVIRUS TYPE 4 AND TYPE 7 VACCINE, LIVE, ORAL

UI: PG

**Manufacturer:** TEVA WOMEN'S HEALTH, INC.

**Distributor:** 

#### LOT / SN:

346000863460008834600122 346001233460012434600125 346001343460013534600149 346001503460016134600175 346001763460017734600186 346001873460019934600209 346002103460021234600244 346002453460024634600254

34600266

#### NOTE 1:

Lot #34600086 - New Expiration Date - April 2015; Lot #34600088 - New Expiration Date - March 2015; Lot #34600122 - New Expiration Date - August 2015; Lot #34600124 - New Expiration Date - October 2015; Lot #34600123 - New Expiration Date - April 2015; Lot #34600125 - New Expiration Date - November 2015; Lot #34600134 - New Expiration Date - October 2015; Lot #34600135 - New Expiration Date - January 2016; Lot #34600149 - New Expiration Date - March 2016; Lot #34600150 - New Expiration Date - March 2016; Lot #34600161 - New Expiration Date - June 2016; Lot #34600175 - New Expiration Date - July 2016; Lot #34600176 - New Expiration Date - August 2016; Lot #34600177 - New Expiration Date - August 2016; Lot #34600186 - New Expiration Date - March 2016; Lot #34600187 - New Expiration Date - October 2016; Lot #34600199 - New Expiration Date - November 2016; Lot #34600209 - New Expiration Date - January 2017; Lot #34600210 - New Expiration Date - January 2017; Lot #34600244 - New Expiration Date - June 2017; Lot #34600245 - New Expiration Date - June 2017; Lot #34600254 - New Expiration Date - August 2017; Lot #34600266 - New Expiration Date - January 2018

## **Service/Additional Instructions:**

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# **Additional Message Recipients:**

## Please ensure dissemination of this information to the following:

Command Channels Immunization Clinics Medical Log Officers Medical Staff Pharmacy Officers Supply Officers Supported Activities/Centers

# **Message Dissemination Authorization**

AF Activities Will Take Action As Prescribed In AFI 41-209, Medical Logistics Support, Chapter 3. For MACOMS & NGB--This Msg Has Been Transmitted To All Designated Subordinate Medical Activities.

See Army Regulation (AR) 40-61, 28 January 2005, Chapter 4, and The Department Of The Army Supply Bulletin (SB 8-75-11) For Applicable Policies and Procedures.

DODD 5105.22 and DODD 6025.13

# **Additional Documentation / Attachments**

MMQC-15-2022 1.pdf

\*\*\* END OF MESSAGE \*\*\*