

TEVA WOMEN'S HEALTH, INC

November 11th, 2015

Christina Izzi
Contracting Officer
DLA Troop Support

Re: 36 Month Expiry of Adenovirus Type 4 and Type 7 Vaccine, Live, Oral

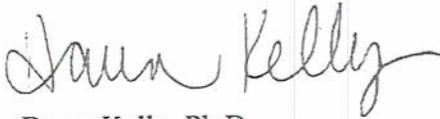
Dear Christina,

I wanted to inform you that Teva has completed the 36 month stability studies on Adenovirus Type 4 and Type 7 Vaccine, Live, Oral. This stability data was submitted to the FDA in a Prior Approval Supplement on 6 Feb 2015. On 5 June 2015, the FDA approved the extension of the vaccine expiry from 30 months to 36 months. Approval of the expiry extension is applicable to all commercial vaccine batches including those batches that were manufactured prior to the expiry extension as these batches were manufactured and tested by the same commercially approved process. The following batches are impacted:

Carton Lot Number	AV4 Lot Number	AV7 Lot Number	Number of Bottles Available for Shipping	Expiration Date	New Expiration Date
34600086	34600067A	34600082A	334	Oct-14	Apr-15
34600088	34600066A	34600083A	361	Sep-14	Mar-15
34600122	34600096A	34600084A	260	Feb-15	Aug-15
34600124	34600095B	34600105B	303	Apr-15	Oct-15
34600123	34600067B	34600082B	34	Oct-14	Apr-15
34600125	34600097B	34600106B	329	May-15	Nov-15
34600134	34600095B	34600106B	29	Apr-15	Oct-15
34600135	34600116B	34600107B	313	Jul-15	Jan-16
34600149	34600117A	34600145A	342	Sep-15	Mar-16
34600150	34600118A	34600147A	353	Sep-15	Mar-16
34600161	34600158A	34600146A	335	Dec-15	Jun-16
34600175	34600157A	34600166A	347	Jan-16	Jul-16
34600176	34600159A	34600165A	367	Feb-16	Aug-16
34600177	34600160A	34600167A	358	Feb-16	Aug-16
34600186	34600118A	34600166A	17	Sep-15	Mar-16
34600187	34600181A	34600168A	366	Apr-16	Oct-16
34600199	34600182A	34600194A	361	May-16	Nov-16
34600209	34600213A	34600193A	313	Jul-16	Jan-17
34600210	34600215A	34600195A	348	Jul-16	Jan-17
34600212	34600214A	34600196A	354	Aug-16	Feb-17
34600244	34600235A	34600222A	335	Dec-16	Jun-17
34600245	34600233A	34600223A	362	Dec-16	Jun-17
34600246	34600234A	34600224A	353	Dec-16	Jun-17
34600254	34600236A	34600250A	361	Feb-17	Aug-17
34600266	34600260A	34600251A	330	Jul-17	Jan - 18

Please let me know if you have any questions.

Sincerely,



Dawn Kelly, Ph.D
Associate Director, Regulatory Affairs CMC
Teva Branded Pharmaceutical Products R&D