

**IMPORTANT INFORMATION REGARDING SANOFI PASTEUR'S  
ADACEL<sup>®</sup> TETANUS TOXOID, REDUCED DIPHTHERIA TOXOID AND  
ACELLULAR PERTUSSIS VACCINE ADSORBED, AND  
DECAVAC<sup>®</sup>, TETANUS AND DIPHTHERIA TOXOIDS ADSORBED  
IN PREFILLED SYRINGES**

October 27, 2010

Dear Health-Care Professional:

This letter is to inform you of an important change to the Prescribing Information (PI) that impacts all lots of ADACEL (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed) and DECAVAC (Tetanus and Diphtheria Toxoids Adsorbed) vaccines in pre-filled syringes.

The previously approved labeling for these products stated that the products were latex-free. However, recently the US Food and Drug Administration notified affected vaccine manufacturers, including sanofi pasteur, that after completing a review of the "latex-free" claim made by the manufacturer of the syringe tip caps used to cover the tips of prefilled syringes (syringes that are shipped with no needle attached), it was concluded that the documentation was inadequate to support that claim. As a result, FDA has mandated that the PI for such products be revised to note that **"the syringe tip caps may contain natural rubber latex, which may cause allergic reactions in latex-sensitive individuals."**

Because the prefilled syringe presentations of ADACEL and DECAVAC vaccines are affected by this change in labeling, you need to be aware that the tip caps of ADACEL or DECAVAC prefilled syringes may contain natural rubber latex. No other components of any presentation of ADACEL or DECAVAC vaccines contain latex, so if you or your patients have concern about this change in labeling, please feel free to make use of the vial presentations of these products. Updated prescribing information may be obtained from [www.vaccineshoppe.com](http://www.vaccineshoppe.com).

We are aware of the inconvenience this labeling change may cause you and we have made it a high priority to address this issue in order to once again offer a pre-filled syringe presentation that is latex-free. We will inform you when that product is available.

For recommendations from the Centers for Disease Control and Prevention regarding latex, latex allergy, and vaccination, please see the attached excerpt from the General Recommendations on Immunization. If you have any questions concerning latex allergy or this change in labeling, please call 1-800-VACCINE. We appreciate your attention to this matter.

Sincerely,

Michael D. Decker, MD, MPH  
Vice President, Scientific & Medical Affairs and Chief Medical Officer