



April 2014

Dear Health Care Provider:

As a valued customer, I am writing to inform you of an update to Sanofi Pasteur's packaging for ActHIB<sup>®</sup> (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]). Last year, we started changing our National Drug Codes (NDC) and labeling in order to comply with the Food and Drug Administration's (FDA) regulations. Sanofi Pasteur is establishing new NDC and lot numbers for the carton and the inner components of the vaccine packages, as well as modifying the carton to incorporate dividers between each of the vials and diluent to prevent movement within the box. As we continue to phase new packaging into the market, you may receive product with old packaging for a brief period of time. ActHIB vaccine will have 3 separate NDC numbers and 3 separate lot numbers, 1 of each for the carton, vial, and diluent. We will begin converting to these new codes for ActHIB vaccine in April 2014.

The NDC is a unique, 3 segment number which serves as a universal product identifier for human drugs. Currently, Sanofi Pasteur products utilize the same NDC on the outer carton (unit-of-sale) as the unit-of-use. Moving forward, the FDA is requiring all manufacturers to assign unique NDCs for the unit-of-sale and unit-of-use. This means the carton, vaccine vial, and diluent will all have different NDC numbers. To help limit the impact on providers, Sanofi Pasteur will be maintaining the current NDC on the unit-of-sale, while creating new NDCs for our product's unit-of-use.

The ActHIB vaccine carton NDC will remain the same as noted above, but the vial and diluent NDC numbers will be changed to the following:

Carton: 49281-545-05

ActHIB vaccine vial: 49281-547-58

Diluent: 49281-546-05

The ActHIB vaccine carton will always contain an 'A' at the end of the lot number; the first 7 characters of the ActHIB vaccine vial will be the same as on the carton. Both the ActHIB vaccine vial and diluent will be 1 letter shorter than the carton lot number. For example:

Carton: UC345ABA

ActHIB vaccine vial: UC345AB

Diluent: UD789AA

Ordering on VaccineShopper.com<sup>®</sup> will remain the same and please continue to record lot numbers as you normally would.

### **Use of NDCs on Payer Claims**

CPT<sup>®a</sup> Codes will continue to be the primary code for submission of vaccine claims. Since most payers do not require the use of an NDC when submitting for vaccine claims, there should be limited impact to coding and billing for your practice. However, you should check with your payers that do require NDC to be sure you are using their preferred NDC (unit-of-use or unit-of-sale). As noted above, payers requiring NDC usually require the 11-digit format. For Sanofi Pasteur products, add a "0" to the middle set of digits in the code to total 11 digits. For example, ActHIB vaccine 49281-545-05 will be billed on a claim as 49281-0545-05.

To help ensure that payers are aware of all NDCs associated with our products, Sanofi Pasteur is working with pricing publications such as First Data Bank<sup>®</sup> and MediSpan<sup>®</sup> to include the NDCs for both the unit-of-sale and unit-of-use. We have also requested that payer payment systems requiring NDC recognize and accept all NDCs for each product.

Should you have questions or require additional information, please contact your Vaccine Specialist, our Customer Account Representatives, or our Reimbursement Support Services at **1-800-VACCINE** (1-800-822-2463). Please visit [www.vaccineshopper.com/NDC](http://www.vaccineshopper.com/NDC) for additional resources and continual updates on the status of each product's NDC change.

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Sanofi Pasteur appreciates your understanding as we work to comply with FDA regulations. We look forward to continuing to serve you and your patients.

Sincerely,

A handwritten signature in black ink, appearing to read 'W. L. Averbeck', written in a cursive style.

William L. Averbeck  
Vice President, Marketing US

<sup>a</sup> CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.

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