Fresenius Kabi Unit-of-Use NDC Change and Barcode Updates

Dear Valued Partner / Healthcare Provider:

**** Please forward this update to the Serialization or Informatics Lead at your company ****

This communication outlines our plans for communicating the Unit-of-Use NDC changes and barcode updates for our products. The barcode updates are being made to facilitate compliance with the DSCSA and serialized data exchange.

Please note the following:

1. Per FDA expectations, Fresenius Kabi is creating a new NDC on the Unit-of-Use when it is sold in a multi-pack (Unit-of-Sale is greater than 1). This is driving the following changes:
   - The Unit-of-Use UPC-A barcode will be updated to reflect the new NDC.
   - For some of the Fresenius Kabi products, the same UPC-A barcode was used on both the Unit-of-Use and Unit-of-Sale even if the quantities were different. Therefore, the current UPC-A barcode on the Unit-of-Sale will be converted to a GS1-128 linear barcode with a new package indicator digit in the GTIN-14.
   - **The Unit-of-Sale NDC will not change. This is the NDC that is listed in the package insert and that is used when ordering the product.**
2. Fresenius Kabi is also changing the package indicator digit in the GTIN-14 at the homogenous case level for some products.

As noted in above we will be transitioning from a zero based to a non-zero based package indicator digit for the GTIN-14 at the Unit-of-Sale for multi-pack products. ***During this transition, the package indicator digit in the GTIN-12 in the current UPC-A barcode on the side tray label at the Unit-of-Sale will not match the package indicator digit in the GTIN-14 in both the 2D data matrix and the GS1-128 linear barcode that are used for serialization and are present on the new top tray.*** The UPC-A barcode on the side tray label will be replaced with a GS1-128 linear barcode encoding the GTIN-14 with the new package indicator digit within the next 18 months. We ask that you please note this and inform your operations team of this discrepancy during the transition. **Figures 1 – 3 at the end of this letter illustrate the product labeling through the transition period.**

Product specific changes are referenced in the attached chart (Attachment A). Products with these changes have been released, or will be released shortly, to our distribution centers. This means you may receive product with the changes described above in the near future.

Please note that there will be a transition phase where product will be on market as both non-serialized and serialized, and with the old artwork and new artwork revisions as described within.

Please communicate these changes, as appropriate, to your customers or trading partners. You may also find the list at ***www.fresenius-kabi.com/us***.

For any questions relating to topics in this letter, please contact: 1.888.386.1300.

This information is also posted at: *www.fresenius-kabi.com/us*.

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We appreciate your support as we incorporate these changes. We look forward to continuing to serve you and your patients.

Sincerely,

Karen Twardzik
Sr. Director, Customer Service Operations & Trade Relations

Figure 1: Interim Top Tray Label Solution for Unit-of-Sale Greater than 1.
Note: The UPC-A on the product side tray label will remain unchanged for an interim period.

Top Tray Label

Side Tray Label

Figure 2: Permanent Solution 1 for Unit-of-Sale Greater than 1.
Note: The product tray label is updated with a GS1-128 encoded with a 14 digit GTIN that matches the 2D barcode.

Top Tray Label

Side Tray Label

Figure 3: Permanent solution 2 for Unit-of-Sale Greater than 1.