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DATE: November 09, 2017
RE: Process Change - Product Label Notification
TO: Valued NEL Client

NEL will be revising the product label formats to align with FDA 21CFR §801.18:

“Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: The year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02.”

While this revision is in process, you may receive media with the current label format of DD-MMM-YYYY (Day-Month-Year - 09NOV2017).

The products are not impacted by this label process and the media performance has not changed.

If you have any questions or concerns, please feel free to contact me.

Best regards,

A handwritten signature in black ink, appearing to read 'Ralph Johnson'.

Ralph Johnson, QA/QC Director
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